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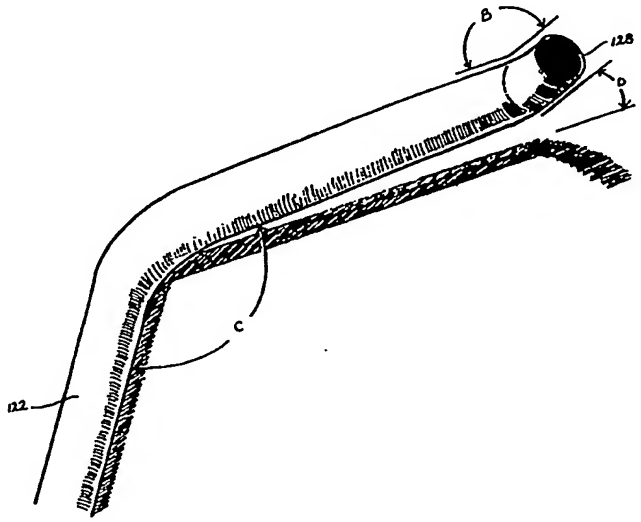
(54) Title: AORTIC BRANCH INTERNAL THORACIC ARTERY CATHETER



(57) Abstract

A method and apparatus for selectively entering and visualizing normal and geriatrically displaced aortic branch arteries comprising a catheter shaft having an outer wall defining a central lumen, the outer wall comprising a first portion having a substantially linear shape, a second portion extending at an angle in a curved manner from the first portion and suitable for providing ease of passage for the catheter from a patient's aorta into a branch artery and optionally having a plurality of apertures extending through the outer wall into the central lumen, and a third portion extending at an out of plane angle and in a curved manner from the second portion and suitable for providing hooked engagement of an aortic branch artery; and a soft deformable catheter tip having a distal central aperture in flow through communication with the central lumen.

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AORTIC BRANCH INTERNAL THORACIC ARTERY CATHETER

Technical Field of the Invention

This invention relates to a method and apparatus to safely, consistently, selectively place a tube or catheter in a normal or geriatrically displaced branch of the aortic arch, the left subclavian artery and left internal thoracic artery (LITA), and the right innominate-subclavian artery and right internal thoracic artery (RITA), in order to visualize arteries pre-operatively and post-operatively and to enlarge the lumen of the RITA and LITA or a graft associated therewith, or a native blocked coronary artery attached to either the right or left internal thoracic arteries.

Background of the Invention

Before the advent of coronary artery bypass surgery (CABG), surgical procedures included dissecting the distal end of a left or right internal thoracic artery (LITA, RITA) from the sternum and chest wall and using the LITA or RITA as a conduit to tunnel into the heart muscle to replenish blood supply secondary to coronary artery blockage in the vessel serving that particular area of myocardium. Long term follow-up demonstrated patency of this conduit, although it improved blood supply to only a very small area of myocardium. This procedure then evolved to another method wherein conduits or grafts, i.e. veins from the legs, are attached surgically from the aorta to native coronary arteries in order to direct blood flow past a more upstream local obstruction and into the native coronary artery. The initial use of a LITA revascularization graft was in 1967, and since that time it has been proven that this graft has the highest patency rate in comparison to vein bypass grafts from the legs.

Angiographic assessment of a left or right internal thoracic artery is important for many reasons, and particularly important in four clinical settings. First, LITA assessment should be performed prior to the insertion of a device to remove arterial obstruction in the proximal left anterior descending coronary artery (LAD), so that if emergency CABG is

necessary, the LITA would already have been evaluated as a possible conduit, if LITA bypass to the LAD or branches is necessary. Similarly, assessment should be performed prior to the insertion of a device to remove arterial obstruction in the right coronary artery, so if emergency bypass surgery is necessary, the RITA would have already been evaluated as a possible conduit, i.e., right coronary artery posterior descending coronary branch of the right coronary artery or marginal branches of the circumflex coronary artery. Such assessment should also be performed prior to coronary artery bypass graft surgery involving potential bypass to the left coronary system, i.e., left anterior descending coronary artery, diagonal coronary artery, or circumflex coronary artery. Additionally, angiographic assessment is recommended following coronary artery bypass graft surgery where the LITA or RITA was used as a bypass conduit. The fourth setting is when a procedure such as percutaneous transluminal coronary angioplasty of the LITA or LITA-anastomosis and RITA or RITA-anastomosis or distal area in the vessel beyond the LITA or RITA insertion is performed.

Atherosclerotic blockage or stenosis of the coronary artery may be successfully relieved using the catheter balloon technique of percutaneous transluminal coronary angioplasty (PTCA). During this technique, a guiding catheter is placed in the origin of the coronary artery and a wire is placed across the coronary artery stenosis followed by a balloon dilatation catheter in the area of stenosis. However, for example, the proximal location of the left anterior descending coronary artery stenosis carries a much lower success rate than PTCA in any other area of this vessel or any other vessel. Indeed, three-month re-stenosis rates may exceed 50 percent in the proximal left anterior descending coronary artery, in contrast to the middle or distal left anterior descending coronary artery or other coronary vessel where the re-stenosis rate at three months is in the 5 to 8 percent range. Moreover, when rapid acute closure occurs, coronary artery bypass surgery mortality rates exceed those performed in a routine scheduled setting. For these reasons, it has been advocated in

proximal left anterior descending coronary artery stenosis that the patient should be offered coronary artery bypass surgery as an alternative. Also, if pre-PTCA LITA or RITA angiography is performed, and either of the internal thoracic arteries is found to be a suitable conduit, then if rapid closure of the PTCA occurs necessitating emergency coronary artery bypass surgery, either the LITA or RITA would be available as the conduit of choice.

To help with the decision making process, each patient considered for coronary artery PTCA should have pre-PTCA LITA and/or RITA angiography. This permits assessment of the LITA/RITA diameter in comparison with the recipient coronary artery. If the diameters or lumens of the LITA or RITA and the coronary artery are perfectly matched, then the patient may be encouraged to choose elective low risk coronary artery bypass surgery using the LITA or RITA as opposed to a vein from the patient's legs. However, recognizing a much lower long term patency rate for saphenous vein bypass grafts (hereinafter referred to as SVBG), if the diameters are mismatched and a saphenous vein is likely to be the conduit, PTCA may be the preferable procedure for coronary artery stenosis.

Most patients undergoing coronary artery bypass surgery have left and right coronary system atherosclerosis, with the average number of vessels bypassed being 3.2-3.5. Therefore, most patients having this surgery will have a LITA or RITA bypass if possible. Pre-surgery internal thoracic artery arteriography should be performed. Such a procedure will provide an assessment of the patency of the left subclavian artery, the right innominate artery, and the right subclavian artery. The LITA arises from the left subclavian artery and any significant atherosclerosis will compromise the flow to the LITA and eliminate it as an acceptable bypass conduit. The RITA arises from the right subclavian artery which arises from the right innominate artery, and any significant atherosclerosis in either of these vessels will compromise the flow to the RITA and eliminate it as an acceptable bypass conduit. Additionally, the

diameters of the internal thoracic arteries will be identified in order to compare each of them with native blocked coronary arteries and decide which vessel(s) would be best suited for the bypass graft. The length of the LITA and RITA is also determined by use of arteriography to see which stenosed arteries can be reached with the LITA or RITA. If a long LITA/RITA has a large distal diameter, the graft may be anastomosed so that the side of the LITA/RITA inserts into the side of a blocked coronary artery (side-to-side anastomosis) and the end of the LITA/RITA is inserted into the side of another blocked coronary artery (end-to-side anastomosis).

Visualization of the LITA/RITA side branches will permit the surgeon and cardiologist to evaluate pre-operatively the vessel and decide how much surgical dissecting is necessary to ligate small side branches and free the vessel from the sternum. If a very large transverse artery side branch is present, a coronary steal syndrome may result whereby blood flow preferentially goes down the transverse vessel to the neck and shoulder muscles (increased with arm and shoulder exercises), instead of down the LITA/RITA to the bypassed coronary artery. The large side branch can be ligated if it is in a position that is surgically accessible. In a significant number of cases, a LITA or RITA may be rejected as a surgical conduit if the side branches cannot be ligated, for example, if it lies under the clavicle.

If no significant side branches are present proximally, the dissection to free up the LITA/RITA pedicle can be limited to just the distal portion of the pedicle. Limiting surgical manipulation is important since excess manipulation may result in external vascular irritation, foreign body giant cell reaction, or late LITA/RITA occlusion. Alternatively, a large distal side branch may be found permitting it to be used as a separate conduit, i.e., the LITA or RITA would end in two equal sized branches, each of which could be used as separate bypass grafts.

Atherosclerosis infrequently develops in either the left or right internal thoracic artery, but surgical manipulation of the LITA and RITA during coronary artery bypass surgery may lead to external factors

causing stenosis or occlusion in the proximal portion of the fragile internal thoracic arteries (hereafter interchangeably referred to as ITA). Although the site of post surgical total occlusion of the LITA/RITA is, accordingly, in the proximal one-third of the conduit, partial stenosis of the LITA/RITA graft is usually at the point where the LITA/RITA is surgically attached to the native coronary artery. PTCA of a stenotic LITA/RITA, anastomosis, or a more distal native vessel has become a successful therapeutic modality for restoring vascular supply to a grafted coronary artery and avoids repeat bypass surgery.

During conventional internal thoracic artery PTCA, under local anesthesia in the groin (or brachial area), a 7, 8, or 9 French guiding catheter is inserted percutaneously into either the femoral or brachial artery and advanced over a guidewire into the left subclavian or right innominate-subclavian and on into the ITA. The large caliber wire is then removed and a small caliber PTCA wire is inserted through the guiding catheter into the LITA or RITA and across the stenosis. A balloon catheter (or other device for removing arterial obstruction) is advanced over the PTCA wire into the area of stenosis and is inflated thus restoring normal blood flow to the area of the heart muscle served by the blocked coronary artery.

The large population of patients undergoing coronary artery bypass surgery for coronary artery system disease requiring LITA or RITA grafts, the assessment of LITA or RITA for PTCA to the proximal left anterior or right coronary artery, circumflex marginal, or diagonal coronary system, and the large number of patients returning for repeat coronary artery bypass surgery, (i.e., one-third of the procedures are in patients whose grafts have closed) all necessitate LITA/RITA angiography.

However, certain geriatric and congenital factors play a role in deterring selective catheterization and angiography of the left and right internal thoracic arteries. In the younger adult the left subclavian arises at a gentle angle from the aorta and is easily entered with a guidewire without manipulation. As the abdominal aorta, lower thoracic aorta and

aortic arch elongate with age, they eventually displace the left subclavian superiorly, anteriorly, and toward the right thorax. Initially this produces an "S" shaped subclavian artery which ultimately results in a severe acute angulation of the left subclavian artery from the aorta. This process alone makes selective catheterization of the left subclavian artery very difficult. Displacement of the left subclavian artery is a common finding in older patients returning for catheterization eight to ten years after coronary artery bypass surgery. So, any new device or method of catheterization must take into account the anatomic aging subclavian artery displacement factor. Similar, but not identical, geriatric and congenital factors play a role in deterring selective catheterization and angiography of the right internal thoracic artery. In the younger adult, the right innominate arises at a gentle angle from the aortic arch. After the age of, approximately, fifty years, the aortic arch elongates and eventually displaces the right innominate superiorly, anteriorly, and toward the right thorax. Initially, this produces a buckling of the right innominate artery which ultimately results in a severe acute angulation of the right innominate artery from the aorta. This process alone makes selective catheterization of the right innominate artery very difficult. As the aging process continues to elongate the aortic arch and further displace the right innominate, the route traversed from the aortic arch to the right innominate, right subclavian, and RITA assumes the configuration of the number 3 rotated counter clockwise 90 degrees. Displacement of the right innominate becomes a common finding in older patients returning for catheterization eight to ten years after coronary artery bypass surgery. Accordingly, any new device or method of catheterization must also consider the unique anatomic aging or geriatric right innominate buckled artery displacement factor.

Considerable congenital variation in the origin of the LITA or RITA from the left or right subclavian artery is also noted. Approximately eighty percent of the LITAs and RITAs arise anteriorly and inferiorly from the left or right subclavian artery respectively. In this location the origin

may be separate or as a common origin with a transverse vessel. Approximately twenty percent of the LITAs or RITAs arise anteriorly and superiorly, not from the left/right subclavian, but from the left/right thyrocervical trunk artery. Also, the LITA and RITA may arise variously from about 1 to 4 centimeters from the ostium of the left subclavian artery and the origin of the right innominate artery.

During selective catheterization of the subclavian innominate or ITA, a dissection or tear in the inside lining of the vessel may occur due to the fragile nature of the vessels. Dissection of the LITA or RITA as a graft has resulted in myocardial infarction.

Recognizing the inherent congenital and geriatric anatomical technical problems with the femoral approach to internal mammary arteriography, a brachial approach alternative has been suggested in which an ipsolateral brachial insertion of a guiding catheter for internal thoracic arteriography was suggested. However, this was associated with complications. For example, three of either procedures were complicated by ventricular fibrillation, cardiac arrest, internal thoracic artery spasm, or dissection.

A special internal thoracic artery catheter to be used by the brachial approach has been suggested in a prior art publication, but the technique has not received acceptance due to risk to the right cerebrovascular arteries, and physican unfamiliarity with PTCA via the brachial approach.

Using commercially available preformed right Judkins coronary catheters, or slightly more angular distal tip catheters, entry into a LITA or RITA from the femoral artery is, with difficulty, at best inconsistently achieved. This approach may also, be associated with vessel trauma. Indeed, as the population of patients requiring ITA selective catheterization and angiography gets older, the geriatric technical factors will further reduce successful instances of cannulation of these vessels.

In a recent publication, a venous injection of contrast with computer digital subtraction angiography of the ITA was suggested. This

method was proposed because of technical difficulties of catheterization of the internal mammary arteries, and to improve visualization in patients with subclavian tortuosity or anomalous LITA/RITA origins. The digital subtraction angiography method was subsequently extended from a venous to an arterial procedure. After a cardiac catheterization, the patient was taken to the X-ray department where an aortic injection of contrast was provided followed by digital subtraction angiography. However, poor visualization of the distal LITA and RITA and, absence of visualization of the bypassed native arteries made the procedure not only an impractical one, but one which fails to meet the criteria established for adequate visualization of the internal mammary arteries. Also, without selective catherization, PTCA could not be performed through this technique.

U.S. Patent 4,909,258 suggested use of a catheter with a distal balloon and proximal port similar to that used years ago for "dry limb angiography". The procedure involves occluding blood flow to the distal subclavian and axillary artery, identifying the ITA, and then entering the vessel through the side port with a guidewire and apparatus to remove vascular obstruction. The disclosed apparatus will not find usefulness to solve the current problems for several reasons. First, the apparatus will not be able to properly enter the displaced left subclavian or right innominate. Most of the patients returning for repeat angiography after LITA/RITA graft surgery are in the older age group where geriatric changes in the left subclavian and right innominate-subclavian have already started to occur. Second, the technique requires inflation of a balloon in an otherwise normal subclavian-axillary artery just distal to the LITA and RITA. It is well known that balloon inflation in a normal artery is considered traumatic. With wire and PTCA manipulation, the balloon may, in itself, produce shear forces sufficient to expose subendothelial tissue and cause thrombogenic trauma leading to the release of tissue factors resulting in stenosis of the vessel. Furthermore, the system described will not offer sufficient support and pushability or ease of

advancement of an apparatus over the wire to remove vascular stenosis. An example of this problem occurs when the apparatus is advanced through the balloon catheter over the wire and into an accordionized LITA/RITA or area of stenosis, resulting in the entire apparatus prolapsing retrograde proximally into the subclavian.

U.S. Patent 4,738,667 describes a coiled catheter for endoscopic-transpapillary exploration of a biliary tract. Thus, the disclosure is of a catheter configured in multiple planes but for a use and in a structural procedural manner which is dissimilar to the device of the present invention.

U.S. Patent 4,169,464 discloses a catheter having a three dimensional tip portion which is formed as an incomplete turn of a coil, or which may be terminated in an extremity which is tangent to, or turned back slightly in a direction generally opposite that of, the winding of the coil turn. The patent describes a device which apparently has usefulness in cannulating certain branches of the abdominal aorta, but not of having the unique structure which permits aortic arch branch catheterization, nor may it be flipped or rotated within a sub branch of the aortic arch, as in the present invention.

Accordingly, a safe and reliable method and apparatus to enter the left subclavian artery and successfully cannulate the LITA is needed to provide complete pre-operative, pre-proximal LAD PTCA, and post-coronary artery bypass surgery angiography and angioplasty for either a normal or displaced left subclavian artery. It has been discovered that the normal or displaced left subclavian artery and variably positioned LITA can be consistently, safely, and selectively catheterized using the apparatus and method of this invention. Also, a safe and reliable method and apparatus to enter the right innominate subclavian artery and successfully cannulate the RITA is needed to provide complete pre-operative angiography, PTCA, and post-coronary artery bypass surgery angiography and angioplasty for either a normal or displaced right innominate subclavian artery system. It has been further discovered that

the normal or displaced right subclavian artery and variably positioned RITA can be consistently, safely, and selectively catheterized using the apparatus and method of this invention.

Another object of the present invention is to selectively simultaneously visualize the left subclavian and LITA artery/graft, right innominate, right subclavian and RITA artery/graft, and associated native/ bypassed blocked coronary arteries without traumatizing the vessels.

Yet another object of the present invention is to provide a strong platform support in order to remove a stenosis in the LITA or RITA artery/ graft or its bypassed native vessel without catheter manipulation and with continuous blood flow to the heart muscle/myocardium through the side hole and end hole combination of the device of the present invention.

Accordingly, this invention is an apparatus and direct method for simultaneously injecting radiopaque media or contrast into a branch of the aortic arch, such as the left and right subclavian, and an internal mammary artery/graft or its bypassed vessels. Preferred catheter characteristics include a soft, deformable short tip; a canted, distal curve on the catheter tip to hook or engage the left subclavian artery or right innominate artery; and a series of primary curves to accommodate the varying ITA-subclavian artery combinations, with side ports in the primary curves, and a firm shaft with pushability into the primary curves. More particularly, preferred catheter characteristics include a curve near one end of the catheter which produces a short distal segment that is out of plane with respect to the remaining catheter shaft portions. When the catheter is placed on a flat surface before an observer, the entire catheter shaft lies in contact with the surface, except that the final curve produces a short segment that extends upward toward the observer to comprise a hooking tip which is out of plane relative to the remainder of the catheter. This out of plane segment enables the physician to readily hook the geriatrically deformed left subclavian or right innominate artery and also

permits the tip to be rotated or flipped within the subclavian between a normal position and an abnormal position, i.e., the common anterior-inferior ITA origin and the thyrocervical trunk origin. In addition, a series of primary curves to accommodate the varying internal mammary artery-subclavian-innominate artery combinations is provided, along with side ports in the primary curves. A firm shaft constructed and arranged for optimum pushability into the primary curves is also preferable, as is a soft deformable tip comprising a distal segment.

This apparatus is preferably percutaneously inserted into the femoral artery over a guidewire and advanced to the ascending aorta. With the guidewire withdrawn into the catheter, the catheter resumes its preformed shape and is rotated and slightly withdrawn until the out of plane and canted segment hooks, for example, the right innominate artery (for RITA). The apparatus is then advanced and the procedure continued until the RITA is cannulated. A similar technique is used for LITA. Radiopaque media is then injected and exits through the side ports to the left or right subclavian and through the distal tip port to visualize a LITA or RITA artery/graft, its branches, and bypassed coronary arteries.

The present invention is also an apparatus and method for enlarging an ITA graft, its anastomosis, or the native vessels served by the ITA graft. A PTCA wire is directed past the side ports and exits through a distal port into the ITA graft and into a native bypassed vessel. A continuous supply of blood flows through the left/right subclavian artery, into the side holes, down the catheter lumen and into the ITA graft, permitting continuous perfusion of the myocardium in the distribution of the bypassed vessel. An apparatus to remove arterial blockage (balloon catheter, atherectomy device, laser catheter, stents, impregnable chemicals, or other means) is then advanced over the PICA wire in the area of obstruction. It is, therefore, yet another object of this invention and apparatus to selectively cannulate the ITA in order to provide an apparatus to remove arterial obstruction while perfusing the distal vessel continuously with oxygenated blood.

Objects and advantages of the present invention in achieving these and other goals will become apparent from the following descriptions, taken in connection with the accompanying drawings, wherein are set forth by way of illustration and example certain embodiments of the present invention.

Summary of the Invention

The present invention involves placing a catheter (tube) with a canted, deformable, atraumatic tip, and end port, and a curved firm shaft with side ports, into the arch of the aorta and into the origin of a normal or displaced subclavian artery and advancing it over a guidewire into the origin of the ITA through a femoral artery puncture site. The soft, gentle, canted, deformable, short tip of the catheter permits atraumatic injection of radiopaque contrast material into the entire destination artery and all of its branches. With respect to the right internal thoracic artery (RITA), the present invention involves placing a catheter with an out of plane distal segment, capable of consistently hooking the right innominate, into the origin of a normal or displaced right innominate subclavian artery and advancing it over a guidewire into the origin of the RITA. The out of plane distal segment of the catheter also permits entry into the anterior inferior or anterior superior location of the RITA to provide injection of radiopaque contrast material in the entire RITA and all its branches. With regard to the left subclavian and innominate, the portion of the catheter comprising the curved shaft with side ports, just proximal to the ITA, permits non-traumatic firm catheter tip support while contrast exists the side ports of the catheter permitting simultaneous visualization of the subclavian innominate and ITA. With the invented apparatus in this same position, other equipment (PTCA balloon, laser, balloon, atherectomy, stent, or impregnable chemicals) to remove or prevent vascular stenosis, may be inserted into the ITA, its anastomosis or a blocked native bypassed coronary artery. The canted, short, non-traumatic deformable tip, and curved firm reinforced shaft insure entry into the left

subclavian, which is frequently markedly displaced to the right, and the right innominate subclavian, which is frequently markedly buckled and also displaced laterally. This is the first common difficult step encountered in selective catheterization of the internal thoracic arteries. A curved catheter shaft lying against the arterial wall opposite to the ITA origin adds significant catheter tip support and safely increases pushability of the inserted device over the guidewire. The side ports permit continuous blood flow to the internal thoracic arteries and bypass vessels during device insertion and manipulation by blood entering the side ports from the left subclavian artery or right innominate subclavian, coursing down the catheter lumen to the deformable end port and into the LITA or RITA.

It has been discovered that the invented apparatus successfully overcomes six major obstacles to safe consistent selective catheterization of the left subclavian, right innominate and internal thoracic arteries. These include the following: (1) the difficult challenge of selectively catheterizing the inconspicuous and geriatric or occult but commonly displaced geriatric left subclavian artery and commonly buckled and displaced right innominate subclavian artery; (2) selective catheterization of the ITA arteries in regard to the varying congenital origin from the anterior inferior subclavian or anterior superior thyrocervical trunk artery; (3) the visualization of a very large proximal origin ITA transverse side branch, transverse Coli or suprascapular artery; (4) catheter tip manipulation and contrast injection without trauma or dissection to the subclavian artery or innominate internal thoracic artery/ graft; (5) simultaneous subclavian, innominate, and ITA radiopaque visualization; and (6) providing a strong, safe platform for the ITA catheter in order to advance an apparatus to remove/prevent arterial stenosis while providing continuous blood supply to the bypassed artery.

The drawings constitute a part of this specification and include exemplary embodiments with the present invention, while illustrating various objects and features thereof. It will be understood

that in some instances relative material thicknesses and relative component sizes and dimensions may be shown exaggerated, to facilitate an understanding of the invention.

Brief Description of the Drawings

Figure 1 is a side elevational diagram of a heart, including the ascending aorta, aortic arch, descending aorta, and abdominal aorta depicting the origin of the arch vessels including the left subclavian artery and the left internal thoracic artery after surgical anastomosis to the left anterior descending coronary artery with total occlusion of the left anterior descending coronary followed by partial stenoses before and after the LITA anastomosis.

Figure 2A is a cross sectional diagram of a normal young aortic arch and its relationship to the origin of the left subclavian artery.

Figure 2B is a cross sectional diagram of the aortic arch depicted in Figure 2A, but showing geriatric growth patterns as the aorta progressively displaces the origin of the left subclavian artery into the right thorax, producing an "S" shaped left subclavian.

Figure 2C is a cross sectional diagram of the aortic arch depicted in Figure 2B, but showing further geriatric growth wherein severe angulation of the left subclavian artery has occurred relative to the geriatrically displaced aortic arch.

Figure 3A is a cross sectional diagram depicting the less common origin of the LITA from the superior/anterior location arising not from the left subclavian, but from the left thyrocervical trunk.

Figure 3B is a cross sectional diagram of the arch of the aorta and the left subclavian emphasizing the common origin of the LITA from the anterior/inferior surface of the left subclavian artery.

Figure 4A is a cross sectional diagram demonstrating the presence of an unrecognized large supra scapular artery branch of the left internal thoracic artery producing a coronary steal syndrome from the LITA anastomosed to the LAD.

Figure 4B is a cross sectional diagram depicting a large transverse cervical artery arising from the proximal LITA producing a coronary steal syndrome from the distal LITA anastomosed to the LAD.

Figure 5 is a cross sectional diagram demonstrating the LITA used to bypass two blocked coronary arteries using side-to-side and end-to-side surgical anastomoses.

Figure 6 is a cross sectional diagram of the LITA used as a surgical graft using two distal branches of the LITA for two separate end-to-side anastomoses to two native blocked coronary arteries.

Figure 7A is a plan view of the apparatus of the present invention depicting the unique canted out of plane end segment with the distal and proximal end ports, side holes in the shaft, and soft deformable radiopaque tip with a single lumen throughout the entire shaft.

Figure 7B is a plan view of the apparatus of the present invention demonstrating the unique out of plane canted distal segment and curve D to hook the displaced left subclavian artery or buckled right innominate artery and to permit the tip to be flipped within the subclavian artery; curve C without ports in place; curve B comprising the final in-plane curve making entry into the internal mammary artery from the subclavian possible; and curve A which marks the entry location of the catheter shaft from the aorta into the target artery.

Figure 7C is a plan view of the catheter illustrating an alternative configuration of out of plane curve "D."

Figure 7D is a plan view of the catheter illustrating yet another alternative configuration of curve "D."

Figure 7E is a sectional view of catheter lumen taken generally along line E-E of Figure 7A.

Figure 7F is a plan view of the apparatus of the present invention depicting the unique canted out of plane end segment.

Figure 7G is a plan view of the apparatus of the present invention depicting the unique canted out of plane end segment.

Figure 8A is a cross sectional diagram and a plan view of the apparatus of the present invention inserted into the left subclavian and selectively into the LITA demonstrating the importance of the side ports located within the left subclavian and the end port with soft tip located within the LITA for simultaneous visualization of the left subclavian and LITA without traumatic injury to the vessels.

Figure 8B is a cross sectional diagram of the left subclavian and LITA and plan view of the apparatus of the present invention but without the benefit of the side ports and the soft tip, resulting in all of the force of the contrast injection being exerted on the distal tip and resulting in a tear in the internal lining of the LITA producing a contrast and blood injection into the LITA wall thereby producing a dissecting thrombus which may lead to occlusion of the LITA.

Figure 8C is a cross sectional diagram of the arch of the aorta, left subclavian artery, and the LITA arising anteriorly-superiorly and medially from the left thyrocervical trunk. The catheter is positioned in the LITA emphasizing the importance of curve "B" and the soft tip provided in order to adapt to the consistent internal angle produced by the origin of the left thyrocervical trunk from the left subclavian artery.

Figure 8D is a cross sectional diagram of the left subclavian artery and the anterior-inferior location of the LITA from the left subclavian artery. The importance of curve "B" in permitting the distal catheter tip to adapt to the consistent internal angle created by the left subclavian and the LITA is particularly depicted.

Figure 9 is a cross sectional diagram of the apparatus of the present invention and PTCA balloon wire apparatus with the wire positioned across the LITA graft anastomosis and the partial stenosis in the LAD. The LITA graft is very accordionized, and as the balloon is advanced over the wire, significant resistance and drag is produced with a tendency to displace the tip of the invented catheter apparatus into the left subclavian. These forces are counteracted by the catheter shaft opposite the LITA origin lying against the left subclavian arterial wall counteracting

the forces trying to displace the catheter tip and offering maximum pushability of PTCA apparatus through the invented catheter apparatus.

Figure 10A is a cross sectional diagram of the left subclavian and LITA showing a certain distance of the LITA from the aorta/left subclavian bifurcation, necessitating a series of catheter lengths to accommodate varying distances.

Figure 10B is a cross sectional diagram of the left subclavian and LITA showing a certain distance of the LITA from the aorta/left subclavian bifurcation, necessitating a series of catheter lengths to accommodate varying distances.

Figures 11 (A-L) are cross sectional diagrams of the aortic arch, descending thoracic, abdominal and iliac vessels, and the left subclavian LITA combinations demonstrating serially the method of insertion of the invented catheter.

Figure 12 is a cross sectional diagram of the heart, aortic and iliac areas, left subclavian and LITA. The invented apparatus is seen positioned in the LITA with simultaneous visualization of the left subclavian and its branches, left thyrocervical trunk and its branches, the LITA and its proximal transverse branch, and all other branches of the LITA.

Figure 13 is a cross sectional diagram of the aorta, left subclavian and LITA bypass graft anastomosed to the left anterior descending coronary artery. A PTCA balloon wire apparatus is inserted through the invented apparatus into a blockage in the left anterior descending coronary artery beyond the LITA-LAD anastomosis. The diagram emphasizes the importance of continuous blood flow through the subclavian side holes of the invented apparatus, and said blood flowing along the lumen of the invented apparatus and into the distal end port, surrounded by the soft tip, then exiting into the LITA. Blood flow continues down the LITA to all areas of the bypassed vessel permitting continuous blood supply to the heart muscle during the angioplasty procedure.

Figure 14 is a cross section of the invented apparatus with a PTCA wire inserted into the shaft of a PTCA balloon catheter demonstrating the residual lumen in the invented apparatus permitting blood flow through the side ports and through the remaining lumen in the invented apparatus.

Figure 15 is a cross sectional diagram of the aortic arch and left subclavian with the invented apparatus positioned in the LITA demonstrating blood flow through the side holes via the left subclavian with exit into the LITA with the balloon wire apparatus in place in the LITA.

Figure 16 is a cross sectional diagram of the aorta, left subclavian, LITA bypass graft and left anterior descending coronary artery after there has been successful partial resolution of a blockage in the left anterior descending coronary artery. The PTCA wire remains across the treated partially resolved stenosis while the balloon has been withdrawn into the curve "C" of the invented apparatus in order that the partially deflated unwrapped balloon may occlude most of the side holes in the invented apparatus shaft in order to inhibit contrast exit through these side ports and favor contrast exit into the LITA in order to visualize the area of recent PTCA.

Figure 17 is a cross sectional diagram of the aorta, left subclavian, LITA bypassed graft anastomosed to the left anterior descending coronary artery and the partially resolved blockage in the left anterior descending coronary artery beyond the LITA-LAD anastomosis. While the PTCA wire remains in the catheter shaft through the LITA and across the partially resolved stenosis the partially deflated unwrapped balloon has been withdrawn from curve "C" into the catheter shaft remaining in the aorta in order that the side holes may become uncovered again and permit blood flow to once again course from the left subclavian through the side ports with exit into the LITA and LAD so that a period of observation can occur to make sure that the recently treated angioplasty site does not rapidly close. Should rapid closure occur, the balloon can be

readily advanced over the wire which remains across the partially treated stenosis.

Figure 18 is a side elevation diagram of a heart, including the ascending aorta, aortic arch, descending aorta, and abdominal aorta depicting the origin of the arch vessels including the right innominate and right subclavian artery and the right internal thoracic artery after surgical anastomosis to the right coronary artery with total occlusion of the proximal right coronary artery followed by partial stenoses after RITA anastomosis.

Figure 19A is a cross sectional diagram of a normal young aortic arch and its relationship to the origin of the right innominate artery.

Figure 19B is a cross sectional diagram of the aortic arch depicted in Figure 2A, but showing geriatric growth patterns as the arch of the aorta progressively displaces the origin of the right innominate artery into the right thorax.

Figure 19C is a cross sectional diagram of the aortic arch depicted in Figure 19A and 19B showing further dilatation and lengthening of the aortic arch, between the right and left arch vessels causing the aortic arch to become elevated.

Figure 20A is a cross sectional diagram depicting the less common origin of the RITA from the anterior superior location arising not from the right subclavian, but from the right thyrocervical trunk.

Figure 20B is a cross sectional diagram of the arch of the aorta and the right subclavian emphasizing the common origin of the RITA from the anterior inferior surface of the right subclavian artery.

Figure 21A is a cross sectional diagram demonstrating the presence of an unrecognized large suprascapular artery branch of the right internal thoracic artery producing a coronary steal syndrome from the RITA anastomosed to the RCA.

Figure 21B is a cross sectional diagram depicting a large transverse cervical artery arising from the proximal RITA producing a coronary steal syndrome from the distal RITA anastomosed to the RCA.

Figure 22 is a cross sectional diagram demonstrating the RITA used to bypass two blocked coronary arteries using side-to-side and end-to-side surgical anastomoses.

Figure 23 is a cross sectional diagram of the RITA used as a surgical graft using two distal branches of the RITA for two separate end-to-side anastomoses to two native blocked branch arteries of the RCA.

Figure 24A is a cross sectional diagram of the right subclavian innominate and RITA and plan view of the apparatus of the present invention but without the benefit of the side ports and soft tip resulting in all of the force of the contrast injection being exerted on the distal tip and resulting in a tear in the internal lining of the RITA producing a contrast and blood injection into the RITA wall thereby producing a dissecting thrombus and possible eventual blockage of the RITA.

Figure 24B is a cross sectional diagram and a plan view of the apparatus of the present invention inserted into the right innominate and subclavian and selectively into the anterior inferior located RITA demonstrating the importance of the side ports in the right subclavian innominate and the end port with soft tip into the RITA for simultaneous visualization of the right subclavian-innominate and RITA without traumatic injury to the vessels.

Figure 24C is a cross sectional diagram of the arch of the aorta, right innominate subclavian artery, and the RITA arising anteriorly superiorly and medially from the right thyrocervical trunk. The catheter is positioned in the RITA emphasizing the importance of the out of plane curve in order to adapt to the consistent internal angle produced by the origin of the right thyrocervical trunk from the right subclavian artery.

Figure 24D is a cross sectional diagram of the right subclavian innominate artery and the anterior inferior location of the RITA from the right subclavian artery. The importance of the out of plane aspect of curve D in permitting the distal catheter tip to be flipped to the

consistent internal angle created by the right subclavian and the RITA is particularly depicted.

Figure 25 is a cross sectional diagram of the apparatus of the present invention and the PTCA balloon wire apparatus with the wire positioned across the partial stenosis of the RCA beyond the RITA graft anastomosis. The RITA graft is very accordionized, and as the balloon is advanced over the wire, significant resistance and drag is produced with a tendency to displace the tip of the invented catheter apparatus into the right subclavian. These forces are counteracted by the catheter shaft opposite the RITA origin lying against the right subclavian arterial wall counteracting the forces trying to displace the catheter tip and offering maximum pushability of PTCA apparati through the invented catheter apparatus.

Figure 26A is a cross sectional diagram of the right subclavian innominate and RITA showing a certain distance of the RITA from the aorta/right innominate bifurcation, necessitating a series of catheter lengths to accommodate varying distances.

Figure 26B is a cross sectional diagram of the right subclavian innominate and RITA showing a certain distance of the RITA from the aorta/right innominate bifurcation, necessitating a series of catheter lengths to accommodate varying distances.

Figures 27 (A-L) are cross sectional diagrams of the aortic arch, descending thoracic, abdominal and iliac vessels, and the right innominate subclavian RITA combinations demonstrating serially the method of insertion of the invented catheter.

Figure 28 is a cross sectional diagram of the heart, aortic and iliac areas, right innominate subclavian and RITA. The invented apparatus is seen positioned in the RITA with simultaneous visualization of the right subclavian innominate and its branches, right thyrocervical trunk and its branches, the RITA and its proximal transverse branch, and all other branches of the RITA.

Figure 29 is a cross sectional diagram of the aorta and right subclavian and RITA bypass graft anastomosed to the right coronary artery. A PTCA balloon wire apparatus is inserted through the invented apparatus into a blockage in the right coronary artery (RCA) beyond the RITA-RCA anastomosis. The diagram emphasizes the importance of continuous blood flow through the subclavian innominate side holes of the invented apparatus and said blood flowing along the lumen of the invented apparatus and into the distal end port, through the out of plane tip, then exiting into the RITA. Blood flow continues down the RITA to all areas of the bypassed vessel permitting continuous blood supply to the heart muscle during the angioplasty procedure.

Figure 30 is a cross sectional diagram of the aortic arch and right innominate subclavian with the invented apparatus positioned in the RITA demonstrating blood flow through the side holes via the right subclavian with exit into the RITA with the balloon wire apparatus in place in the RITA.

Figure 31 is a cross sectional diagram of the aorta, right subclavian, RITA bypass graft and right coronary artery after there has been successful partial resolution of a blockage in the right coronary artery. The PTCA wire remains across the treated partially resolved stenosis while the balloon has been withdrawn into the curve C of the invented apparatus in order that the partially deflated unwrapped balloon may occlude most of the side holes in the invented apparatus shaft in order to inhibit contrast exit through these side ports and favor contrast exit into the RITA in order to visualize the area of recent PTCA.

Figure 32 is a cross sectional diagram of the aorta, right innominate subclavian, RITA bypassed graft anastomosed to the right coronary artery and the partially resolved blockage in the right coronary artery beyond the RITA-RCA anastomosis. While the PTCA wire remains in the catheter shaft through the RITA and across the partially resolved stenosis the partially deflated unwrapped balloon has been withdrawn from curve C into the catheter shaft remaining in the aorta in order that

the side holes may become uncovered again and permit blood flow to once again course from the right subclavian through the side ports with exit into the RITA and RCA so that a period for observation can occur to make sure that the recently treated angioplasty site does not rapidly close. Should rapid closure occur, the balloon can be readily advanced over the wire which remains across the partially treated stenosis.

As required, detailed embodiments of the present invention are disclosed herein. It is to be understood, however, that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but rather as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriately detailed system or structure.

Referring to Fig. 1, oxygenated blood exits the left lower heart pump or left ventricle 10 of heart 14 and enters a large trunk artery, the aorta 16, more specifically, the ascending aorta 18. Since the contracting heart muscle cells or myocardium forming the heart chambers cannot exchange oxygen and materials because of the endocardium or cellophane-like lining, the first two arteries arising from ascending aorta 18, the right coronary artery 26 and the left main coronary artery 28 provide conduits to the heart muscle cells. Left main coronary artery 28 divides or bifurcates into the circumflex coronary artery 32 and the left anterior descending coronary artery 34 herein referred to interchangeably as LAD 34. LAD 34 has several large branches called the left ventricular diagonals 35. Subsequent arteries arising from the aortic arch 38 include the right innominate 40, right carotid 42, left carotid 44, and finally the left subclavian artery 46. Thereafter, the descending aorta 50 and the abdominal aorta 52 continue through the abdomen where they bifurcate into the iliac 56 and finally the femoral arteries 58 at the groin area.

When LAD 34 or left ventricular diagonal 35 branch of LAD 34, become partially stenosed, or totally occluded, transient or permanent

decrease in blood supply (ischemia) to the heart muscle cells may occur. This results in transient or permanent reduction in heart pump, i.e. left ventricular 10, contractility.

To restore blood supply to transient ischemic myocardium, the distal left internal thoracic artery may be dissected free of the chest wall and surgically attached or anastomosed to the downstream blocked coronary artery. Thus, LITA 64 is used as a conduit to carry blood from aortic arch 38 to left subclavian 46, to the LITA anastomosis graft 68, and into the vessel beyond the obstruction.

Left subclavian artery 46 springs from aortic arch 38 as its last major branch before the aorta descends into the thorax as the thoracic descending aorta 50. In the first five decades of life, left subclavian artery 46 is easily entered with a guidewire 74 inserted percutaneously into femoral artery 58, as is shown in Figure 2A. In this age group left subclavian artery 46 is almost in a direct line in the descending aorta 50 and abdominal aorta 52. By about the fifth or sixth decade, at a time when atherosclerotic disease/bypass becomes more frequent, the iliac artery 56, the abdominal aorta 52, and the descending thoracic aorta 50 dilate, elongate, and accordionize. As a result of these geriatric growth patterns and the accordionization of the distal abdominal aorta 52, aorta arch 38 starts to shift toward the right thorax and drags with it the origin 78 of left subclavian artery 46. Initially, displaced left subclavian artery 46 produces an "S" shaped deformity in left subclavian 46. Thereafter, with continued arch dilation and displacement toward the right thorax, an acute angle 80 is formed by left subclavian origin 78 and aortic arch 38. Recognizing the significance of these progressive geriatric aortic vascular changes was quite significant in discovering the apparatus disclosed in this invention, for which there is no other known catheter designed to properly accommodate such changes.

Left subclavian artery 46 provides left vertebral artery 84, serving the back of the brain and the spinal cord, the left thyrocervical trunk artery 86, serving the neck and upper shoulder muscles and skin

and LITA 64. The left internal thoracic artery 64 springs from the area behind the collar bone on the anterior-inferior surface of left subclavian artery 46 in about 80 percent of individuals, as illustrated in Figure 3B. However, in about 20 percent of individuals, the LITA arises from left thyrocervical trunk artery 86. This latter anterior-superior location of LITA from left thyrocervical trunk artery 86 is not obvious, but is predictably present when LITA 64 does not arise from left subclavian 46 in its more common anterior-inferior location. Due to these congenital and geriatric vascular growth patterns, the distance between the origin of left subclavian 46 from aorta 38, and the distance of LITA 64 from left subclavian 46 may vary by 1 to 4 centimeters. Recognizing the non-obvious import of these common congenital and geriatric variations of LITA 64 was important in designing and discovering the apparatus and method of this invention.

The very proximal portion 94 of LITA 64 may give origin to a large transverse branch artery, i.e. left supra scapular artery/left transverse scapular artery 98, or the left transverse Coli/left transverse cervical artery 100. When LITA is used as a bypass conduit and there was a pre-operative unidentified large supra scapular or transverse Coli artery, then a coronary steal syndrome may develop. In the post-surgical LITA-LAD bypass setting, exercise initiated increased blood flow to the left neck, shoulder, and back muscles preferentially steals blood out of the proximal LITA and into the supra scapular or transverse Coli artery, thus depriving the LITA-LAD system of blood supply. This may then result in myocardial ischemia reproducing the exact events which initially led to LITA-LAD bypass in the first place. However, if pre-operative angiography identifies this anatomy, the LITA may be properly rejected as a possible conduit and alternative therapeutic choices may be explored. Also, absence of significant sized LITA side branches may permit the cardiac surgeon to limit the dissection and reduce trauma to the LITA in freeing it from the chest wall. Further, the length, diameter, and size of

the very distal LITA branches determines if the vessel may be used as a side-to-side anastomosis or an upside down "Y" anastomosis.

Accordingly, the injection of contrast to provide radiopaque visualization of the left subclavian, LITA artery/graft, and distal bypass vasculature provides information for critical pre-operative and post-operative decision making. In the pre-operative setting, the visualization demonstrates the presence or absence of stenosis of the left subclavian artery. If such stenosis is present, it will preclude use of LITA as a conduit. The visualization also reveals the presence of a proximal large transverse vessel that could result in a post-operative coronary steal syndrome, as discussed hereinabove. Information is also revealed through visualization regarding the LITA diameter, length, and size of distal vessel and therefor the possibility of bypassing to several native blocked coronary arteries rather than to only a single vessel.

In the post-operative setting, the presence or absence of left subclavian artery stenosis is determined through visualization. Such stenosis, if present, would be a possible cause of reduction of blood supply to the LITA and resulting myocardial ischemia. The patency of the LITA graft is also determinable. Although atherosclerosis hardly ever develops, inflammatory total occlusion or partial stenosis may occur at the most superior surgical dissection site. Patency of the LITA-coronary anastomosis is observable, as well as the structural integrity of the bypassed coronary artery. Further, the device provides a support platform for insertion of an apparatus or chemical to remove arterial plaque.

Accordingly, the present invention takes into consideration the unobvious geriatric and congenital variations of the left subclavian, and the left internal thoracic artery. The invention also provides an apparatus and a method to more safely, effectively, selectively catheterize the LITA and the left subclavian artery, visualize them simultaneously, and provide a strong, safe support platform in order to accomplish insertion of interventional therapeutic apparatus to remove and/or prevent arterial obstruction.

Referring to Figs. 7A-7E, the apparatus of the present invention is disclosed comprising a catheter 104 having a single proximal end port 106 and hub 108 for radiopaque contrast injection or interventional apparatus insertion. Catheter 104 has a single continuous lumen 112, a single distal end port 114 (or ports) for exit of contrast and interventional apparatus into the LITA, and a series of side ports 118 in a generally curved portion 122 (and/or sub-portions) of the catheter shaft 124 constructed and arranged for permitting continuous blood flow during LITA cannulization via the left subclavian artery or right subclavian innominate artery into the side ports. The blood then flows through catheter lumen 112 and exits through single distal end port 114 into the LITA/RITA.

Referring to Figure 7F, the distal segment of the present invention is further disclosed. The in plane angle B created by the curve of the distal segment 128 and the main catheter shaft 122. The length of the distal segment 128 may comprise curve radii of between 2-25mm, although a more preferable range is 4-15 mm. The distal segment is placed out of plane to the main catheter shaft curve D, such that if the entire apparatus of the present invention is placed on a table, the main catheter shaft 122 will lie flat (main catheter shaft plane) upon the table while the catheter distal segment 128 will arise up and away from the table thus forming an out of plane (curve D) distal catheter shaft segment. The angle created between the table and the distal segment, comprising angle or curve D, may vary from +1 to +179 degrees and -1 to -179 degrees to adapt to various origins of the right innominate (left subclavian) from the aortic origin. A more preferable range is $\pm$ 30 degrees to $\pm$ 90 degrees. This out of plane distal segment 128 (curve D) could enable even less experienced physicians/technicians to hook or engage the normal or displaced right innominate or left subclavian and place the catheter tip in the right (left) subclavian. By selecting the appropriate distal segment length and out of plane curve, the physician/technician will also be able to flip or rotate this distal segment

into the RITA/LITA between either the common anterior-inferior subclavian origin or the less common anterior-superior location from the thyrocervical trunk artery.

In Fig. 8A, the present invention is embodied without side ports 118 and hinged deformable soft tip 128. In Fig. 8A, all the power applied with the hand injection of contrast to catheter lumen 112 is delivered to distal end port 114. If the catheter tip is not perfectly aligned with lumen 112 of the LITA, then injection of contrast may result in a tear of artery wall 132 and subsequent contrast and blood will develop between the linings of arterial wall 132 as a dissecting thrombus. This will often lead to occlusion of the LITA lumen 112. With side ports 118, and a hinged deformable soft tip 128, the pressure of the contrast injection is dissipated through side ports 118 into left subclavian 46, and through end port 114, into the LITA (preventing injury to the LITA), and visualizing the left subclavian.

In large part to achieve the above objectives, it has been discovered that the distal catheter shaft, generally depicted at 136, preferably uses a plurality, and most preferably four specific curves, as shown in Fig. 7D, to meet the demands placed on the apparatus. Curve "B" is designed to comply with the natural and consistent internal angle of LITA/RITA 64 from thyrocervical trunk 86 found in 20 percent of individuals or the internal angle formed between the left (right) subclavian and the LITA (RITA).

Curve "D" is an out-of-plane cant placed on distal catheter segment and tip to engage or hook a normal or displaced left subclavian artery 46, and to facilitate entry into the LITA 64 from the anterior-inferior left subclavian origin 46, or the anterior superior origin orifice 142 of LITA 64, from the left thyrocervical trunk 86 as shown in Figures 8B and 8C.

Curve "C", also shown in Fig. 7D, is a gentle curve placed in catheter shaft 124 in order to position the firm shaft against the subclavian-innominate artery wall 132 opposite the ITA origin 142 as shown in Figures 8C and 8D. It has been discovered that this curve "C"

permits the operator to have maximum pushability with an intervention apparatus as it is advanced over the PTCA wire. With an accordionized ITA, which is common pre-operatively and post-operatively, considerable drag is offered as the interventional apparatus is advanced over the wire, and there is a great tendency to displace the guiding catheter tip outward into the subclavian. With the apparatus of this invention, the forces of resistance that try to displace guiding catheter tip 138, from the ITA origin, are easily counteracted by catheter shaft 124, i.e., that portion of shaft 124 comprising curve C lying against the arterial wall 132 opposite the LITA (RITA) origin 142.

Curve A properly positions catheter 104 in left subclavian 46 (or right innominate) at its origin 78 from aorta 16. Referring to Figs. 7B and 10, the length of the shaft comprising curve "C" is 2, 3, 4, or 5 centimeters, etc., according to the distance of LITA 64 from the left subclavian-aortic or right innominate-aortic bifurcation.

Accordingly, distal catheter tip 138 preferably comprises a pliable atraumatic tip 128 molded securely to catheter shaft or stem 138. Catheter proximal hub 108, its lumen 112, side ports 118, and end port(s) 114 may be formed by conventional techniques standard in the catheter industry. Distal atraumatic soft tip 128 is readily produced by conventional techniques of standard material in the soft tip catheter industry, although with certain structural features of hingability and method use as incorporated in a novel manner according to the present invention. Bonding of proximal hub 108 and distal soft tip 128 to catheter 104 are also techniques standard in the catheter industry. A conventional radiopaque material is commonly blended into the shaft and tip to allow exact X-ray fluoroscopic location and orientation of the catheter and its soft tip.

A method and apparatus is disclosed for placing a catheter with a canted, deformable, atraumatic tip, end port, and a curved firm shaft with side ports, into the origin of a normal or displaced left subclavian artery and advancing it over a guidewire into the origin of the

internal thoracic artery through a femoral artery puncture site. The soft, gentle, canted, optionally radiopaque deformable, short tip of the catheter permits atraumatic injection of radiopaque contrast material into the entire left internal thoracic artery and all of its branches. In the subclavian the curved shaft with side ports, just proximal to the left internal thoracic artery, permits non-traumatic firm catheter tip support while contrast exits the side ports of the catheter allowing simultaneous visualization of the left subclavian and left internal thoracic artery.

A method and apparatus is also disclosed for placing a catheter with an out of plane distal segment into the aortic arch to hook the origin of a normal or geriatric displaced right innominate subclavian artery through a femoral artery puncture site. A method and apparatus is further disclosed wherein the novice physician technician can flip, twist, or rotate the distal out of plane segment within the subclavian artery between either of the congenital RITA origins permitting subsequent atraumatic injection of radiopaque contrast to simultaneously visualize the RITA/branches/artery graft and subclavian innominate artery.

Referring now to Figures 11A-11F, there is disclosed the techniques for cannulating the LITA and using the apparatus of the present invention. The process involves percutaneous insertion of a "J" tipped guidewire into the femoral artery, and then advancing it under fluoroscopic control past left subclavian artery origin 78 into a proximal portion of aortic arch 38. Holding the proximal end of the wire, catheter 104 is threaded over guidewire 74 into the proximal portion of aortic arch 38 beyond the left subclavian origin 78. Thereafter the wire is withdrawn into the catheter shaft in a manner sufficient to prevent deformation of the catheter curves. Catheter 104 is slowly rotated and withdrawn until soft deformable atraumatic tip 128 hooks the normal or displaced left subclavian artery origin. Guidewire 74 is then again advanced into catheter 104 until it deforms and straightens out distal soft tip 128. The flexibility and hinge-like characteristics of the curves B and D, joining the soft, pliable tip 128 to distal catheter tip 138,138' permits curves B and D

to straighten, thus offering the least resistance to wire advancement, into left subclavian artery 46. This also minimizes any recoil of the catheter tip out of the displaced left subclavian artery. The guidewire is then positioned past the origin of the LITA, as illustrated in Figure 11F.

Guidewire 74 is then withdrawn into catheter 104 apparatus so that it is not deforming any of the curves. Catheter 104 is then rotated and withdrawn slowly. If the catheter does not enter the LITA, it is presumed that the LITA is arising from the left thyrocervical trunk 86. In such instance, guidewire 74 is repositioned past the LITA origin 142 into the distal left subclavian artery, and catheter 104 apparatus is again advanced over guidewire 74 into this position. Guidewire 74 is then withdrawn into the apparatus such that it is proximal to all the catheter curves. The catheter is then again slowly rotated preferably in the opposite direction from previously and withdrawn until it enters the left thyrocervical trunk 86. Slight advancement of catheter 104, thereafter, permits entry into the anteriorly-superiorly located LITA arising from the left thyrocervical trunk.

With the apparatus of the invention positioned as illustrated in Fig. 12, angiographic radiopaque contrast is injected into proximal end port 106. This material flows through catheter lumen 112 and exits first through side ports in left subclavian 46 and finally through the end port 114 surrounded by soft deformable tip 128. This permits complete visualization of the entire left subclavian-LITA and the branches simultaneously.

Embodied in Fig. 13, the catheter 104 of the present invention is shown inserted through a percutaneous insertion in the right common femoral artery 58 and following the accordionized iliac artery 56, the abdominal aorta 52 and thoracic aorta 54, and into the geriatrically displaced left subclavian artery 46. The device is shown selectively inserted into an anterior-inferior located LITA 64. The LAD 34 is totally occluded at 160 and the LITA 64 has been surgically anastomosed at 164 distal to original total occlusion 160. A new, or unrecognized, pre-

operative stenosis at 168 beyond LITA-LAD anastomosis 164 is visualized by injection of contrast. A guidewire 74 is then advanced through the catheter shaft into LITA 64 and LAD 34, and across new stenosis 168. An apparatus to remove arterial stenosis (such as a PTCA balloon 172, atherectomy device, impregnable chemical, or the like), is advanced over the wire, through the LITA, and into the new stenosis. The tip 128 of catheter 104 of the present invention will completely occlude blood flow around the catheter into the LITA. Thus, the plurality of side ports 118 provides continuous blood profusion of the coronary circulation by blood entering the side ports in subclavian artery 46 and exiting the end port 106 into LITA 64. Fig. 14 demonstrates an exemplary relative cross-sectional area available for blood to enter side ports 118 and flow through the invented guiding catheter 104 lumen 112 even with a PTCA balloon 172 and PTCA wire 74 in place.

In Fig. 15, the guiding catheter 104 of the present invention has an exemplary internal available lumen of .065 - .080 inches depending on the French size chosen. The external diameter of a usual balloon catheter shaft ranges from .022 inches (1.7 French) to .060 inches (4.5 French) with the average shaft being .039 inches (3 French). Even with the smallest diameter guide, this will leave .026 inches for blood to enter a side port 118 around balloon catheter 104 shaft and travel along the lumen of the invented apparatus to exit through end port 114 in the LITA 64.

It has been discovered that after reduction of the vascular stenosis, shown in Fig. 16 at 168, the deflated balloon 172 has a somewhat larger residual diameter in that it does not completely deflate and wrap as it did before it was inflated the first time. This deflated balloon can be withdrawn into the invented guiding catheter 104 adjacent to side ports 118 while the guidewire 74 remains in the distal LAD 34 beyond the partially removed stenosis 168. This technical maneuver partially permits deflated balloon 172 to cover most of the sideholes and markedly reduces contrast exit through the side holes 118 and favors the dye exiting distal end port 114 into LITA 64 to maximize visualization in the area of the

resolved LAD stenosis. Further withdrawal of the balloon into the catheter shaft, as shown in Fig. 17, will restore blood supply to LITA 64 via the uncovered side holes 118 and permit observation of the treated stenosis. This ensures that rapid closure does not occur, yet it provides fresh, oxygenated blood to the myocardium while the PTCA wire remains across the area of treatment. Figures 30-32 disclose a similar course but for the procedure utilizing the right internal thoracic artery.

Referring to Figure 18-32, the method and apparatus of the present invention is disclosed in the context of the right internal thoracic artery system. In Figure 18, oxygenated blood exits the left lower heart pump or left ventricle 310 of the heart 314, and enters a large trunk artery, the aorta, more specifically, the ascending aorta 318. Since the contracting heart muscle cells or myocardium forming the heart chambers cannot exchange oxygen and materials because of the endocardium or cellophane-like lining, the first two arteries arising from ascending aorta 318, the right coronary artery (RCA) 326 and the left main coronary artery 334, provide conduits to the heart muscle cells. Left main coronary artery 334 divides or bifurcates into the circumflex coronary artery 332 and the left anterior descending coronary artery 335 herein referred to interchangeably as LAD. Subsequent arteries arising from the aortic arch 338 include the right innominate 340, left carotid 344, and finally the left subclavian artery 346. Thereafter, the descending aorta 354 and the abdominal aorta 352 continue through the abdomen where they bifurcate into the iliac 356 and finally the femoral arteries, 358 at the groin area.

When the RCA 326 becomes partially stenosed 358, or totally occluded 360, transient or permanent decrease in blood supply to the heart muscle cells may occur. This results in transient or permanent reduction in heart muscle pump capability, (left ventricular contractility).

To restore blood supply to transient ischemic myocardium, the distal right internal thoracic artery 364 may be dissected free of the chest wall and surgically attached or anastomosed to the downstream blocked right coronary artery 326C. Thus, RITA 364 is used as a conduit

to carry blood from aortic arch 338 to right innominate 340 subclavian 348 to the RITA graft and into RCA beyond the obstructions 368, 370.

The right innominate artery 340 springs from aortic arch 338 as its first and largest branch, and takes an oblique, out of plane course upward, backward, and to the right where it bifurcates to form the right common carotid artery 342 and subclavian artery 348. In the first five decades of life, the right innominate 340, right subclavian 348, and RITA 364 are easily entered with a catheter 104, shown in Figure 19, inserted percutaneously into femoral artery 358.

As previously discussed and as shown in Figure 19B, by about the fifth or sixth decade, at a time when atherosclerotic disease and coronary artery bypass surgery becomes more frequent, the ascending aorta 318 and aortic arch 338 dilate, elongate, and accordionize. As a result of these geriatric growth patterns, the arch of the aorta 338 becomes elevated and tortuous, starts to shift toward the right thorax as shown by direction line 379 and drags with it the origin of right innominate artery 340. Tortuosity of the innominate artery 340 and secondary portion 348' of right subclavian artery 348 and right common carotid 342 results. The right subclavian artery 348 tends to anchor the right innominate artery at its bifurcation resulting in buckling when elevation of the aortic arch occurs. Thereafter, as shown in Figure 19C with continued arch dilation (depicted in broken lines) and displacement toward the right thorax (direction arrow 379) an acute angle 380 is formed by the right innominate origin and the aortic arch. The final result of the geriatric changes leaves the arterial tree of the RITA, right subclavian, and right innominate conforming to the Number 3, rotated 90 degrees counterclockwise, highlighted in broken lines at 381. Recognizing the significance of these progressive geriatric aortic vascular changes was quite significant in discovering the apparatus disclosed in this invention, for which there is no other known catheter designed to properly accommodate such changes.

As shown in Figure 20A, right innominate subclavian artery 340 divides into right common carotid artery 342, serving the front of the

brain, and right subclavian artery 371. Right subclavian artery 371 gives origin to the right vertebral artery 384 serving the back of the brain and the spinal cord, the right thyrocervical trunk artery 386 serving the neck and upper shoulder muscles, the skin, and RITA 364. Right internal thoracic artery 364 springs from the area behind the collar bone on the anterior-inferior surface of right subclavian artery 371 in about 80 percent of individuals, as illustrated in Figure 20B. However, in about 20 percent of individuals, RITA 364 arises from right thyrocervical trunk artery 386, as in Figure 20A. This latter anterior-superior location of RITA 364 does not arise from right subclavian 371 in its more common anterior-inferior location. Due to these congenital, Figures 20A-20B, and geriatric, Figures 19A, 19B, 19C, vascular growth patterns, the distance between the origin of RITA from the aortic arch-right innominate bifurcation may vary by approximately 1 to 4 centimeters. Recognizing the non-obvious import of these common congenital and geriatric variations of the right internal thoracic artery was important in designing and discovering the apparatus and method of this invention.

As shown in Figures 21A and 21B, the very proximal portion 394 of RITA 364 may give origin to a large transverse branch artery, i.e., the right suprascapular artery-right transverse scapular artery 398; or the right transverse Coli-right transverse cervical artery 400. When RITA 364 is used as a bypass conduit and there was a pre-operative unidentified large suprascapular 398 or transverse Coli artery 400, then a coronary steal syndrome may develop. In the post-surgical RITA-RCA bypass setting, exercise initiated increased blood flow to the right neck, shoulder, and back muscles preferentially steals blood out of the proximal RITA and into the suprascapular or transverse Coli artery thus depriving the RITA-RCA system of blood supply. This may then result in myocardial ischemia reproducing the exact events which initially led to RITA-RCA bypass in the first place. However, if preoperative angiography identifies this anatomy, the RITA may be properly rejected as a possible conduit and alternative therapeutic choices may be explored. Also, absence of

significant sized RITA side branches may permit the cardiac surgeon to limit the dissection and reduce trauma to the RITA in freeing it from the chest wall. Further, the length, diameter, and size for the very distal RITA branches determines if the vessel may be used as a side-to-side anastomosis 369 to two branches of RCA or an upside down "Y" RITA 370 to two branches of the RCA, depicted respectively in Figures 22, 23.

Accordingly, the injection of contrast to provide radiopaque visualization of the right innominate right subclavian, RITA artery/graft, and distal bypass vasculature, provides information for critical pre-operative and post-operative decision making. In the pre-operative setting, the visualization demonstrates the presence or absence of stenosis of the right innominate, or right subclavian artery. If such stenosis is present, such as depicted at 401 in Figure 18, it will preclude the use of RITA as a conduit. The visualization also reveals the presence of a proximal large transverse vessel that could result in a post-operative coronary steal syndrome, as discussed hereinabove. Information is also revealed through visualization regarding the RITA diameter, length, and size of distal vessel and therefore the possibility of bypassing to several native blocked coronary arteries rather than to only a single vessel.

In the post-operative setting, the presence or absence of right subclavian right innominate artery stenosis is determined through visualization. Such stenosis, if present, would be a possible cause of reduction of blood supply to the RITA, resulting in myocardial ischemia. The patency of the RITA graft, is also determinable. Although atherosclerosis hardly ever develops, inflammatory total occlusion 360 or partial stenosis 401, as shown in Figure 18, may occur at the most superior surgical dissection site. Patency of the RITA right coronary anastomosis is observable, as well as the structural integrity of the bypassed coronary artery, utilizing the device of this invention. Further, the device provides a support platform for insertion of an apparatus or chemical to remove arterial plaque.

Accordingly, the invention provides a method and an apparatus having an out of plane distal segment to hook or engage the geriatric buckled right innominate artery and right subclavian artery, and also to flip or rotate the distal out of plane segment within the right subclavian artery in order to selectively cannulate either of the two congenital origins of the RITA.

In other words, this invention provides a method and an apparatus with an out of plane distal segment to hook any normal or displaced branch of the aortic arch and an out of plane distal segment capable of being flipped within the branches of the aortic arch or one of its sub-branches.

The invention also specifically provides an apparatus and a method to simultaneously visualize the right innominate and right subclavian via exit of contrast through side ports, and to visualize the RITA via exit of contrast from the end port. Thus, the invention also provides an apparatus and method to simultaneously visualize a branch of the aorta and one of its sub-branches while having the tip of the catheter in the sub-selected vessel.

The invention also provides a safe strong platform in order to accomplish insertion of interventional therapeutic apparati to remove and/or prevent arterial obstruction, while side holes permit continuous flow down the RITA.

Figure 24A is a cross sectional view of right subclavian 348, innominate 340, and RITA 364, with (in plan view) catheter 104. No side ports are present, nor is a catheter distal soft tip. This structure presents some likelihood, therefore, that the force of the contrast injection is focused at the distal tip of the catheter - resulting in a tear in the internal lining 364" of RITA 364. Such a tear produces a contrast and blood injection into the wall 365, thereby causing a dissecting thrombus and possible eventual blockage of RITA 364.

Figures 24B is a cross sectional view of right subclavian 348, innominate 340, and RITA 364, with catheter 104 having side ports 118 in

right subclavian 348 innominate 340. End port 114 of soft distal tip 128 and side ports 118 permit simultaneous contrast injection for visualization of the right subclavian innominate and RITA without traumatic injury to vessels, such as wall 365.

Figure 24C is a cross sectional view of right subclavian 348 innominate 340, and RITA 364 arising anteriorly superiorly and medially from right thyrocervical trunk 386. Catheter 104, shown in plan view, is positioned in RITA 364 in a manner which emphasizes the importance of the out of plane curved structure of catheter 104 in order to adapt to the substantially consistent internal angle produced by the origin of right thyrocervical trunk 386 from right subclavian artery 348.

Referring now to Figure 24D, there is shown a further cross sectional view of right subclavian 348 innominate artery 340. The more common anterior inferior position of RITA 364 is also shown. The importance of the out of plane aspect of curve D in permitting distal catheter tip 128 to be flipped to the consistent internal angle created by right subclavian 348 and RITA 364 is particularly illustrated.

Then, referring to Figure 25, the manner in which a PTCA balloon wire 416 is positioned across partial stenosis 358 of RCA 326 beyond the RITA graft anastomosis is shown. The RITA graft is depicted very accordionized, and as balloon 420 is advanced over wire 416, significant resistance and drag is normally produced with a tendency to displace the tip of the invented catheter apparatus into right subclavian 348. These forces are counteracted by the catheter shaft, opposite RITA origin, lying against right subclavian arterial wall 425. In effect, the catheter wall contact counteracts the forces trying to displace catheter tip 128 thus offering maximum pushability of PTCA apparati through catheter 104. Blood flow arrows 428 are also shown.

Figures 26A and 26B representatively illustrates the different distances at which RITA 364 may be located from the aorta-right innominate bifurcation 380. This necessitates availability of a series of catheter 104 lengths to accommodate the varying distances.

Referring now to Figures 27A-27E, there is disclosed the techniques for cannulating the RITA and using the apparatus of the present invention. The process involves percutaneous insertion of a "J" tipped guidewire into the femoral artery, and then advancing it under fluoroscopic control past the right innominate artery origin into the ascending aorta. Holding the proximal end of the wire, catheter 104 is threaded over guidewire 74 into the ascending aorta beyond right innominate artery origin 340. Thereafter, the wire is withdrawn into the catheter shaft in a manner sufficient to permit the catheter to assume its original configuration. Catheter 104 is slowly rotated and withdrawn until the out of plane-distal canted segment hooks the normal or displaced right innominate artery origin, shown in Figure 27D. Guidewire 74 is then again advanced into catheter 104 until it enters the right innominate artery and the right subclavian. The flexibility and hinge-like characteristics of the curves B and D, joining the soft, pliable tip 128' to distal catheter tip 128 permits curves B and D to straighten, thus offering the least resistance to wire advancement into the right innominate, and right subclavian. This also minimizes any recoil of the catheter tip out of the right innominate artery. The guidewire is then positioned past the origin of RITA 364, depicted in Figure 27F, and catheter 104 is advanced along guidewire 74 as shown in Figure 27G.

Guidewire 74 is then withdrawn into the catheter apparatus so that the catheter assumes its original configuration. Catheter 104 is then rotated and withdrawn slowly. If the catheter does not enter the RITA, it is presumed that RITA 364 is arising from right thyrocervical trunk 386. In such instance, guidewire 74 is repositioned past the RITA origin into the distal right subclavian artery and catheter apparatus is again advanced over guidewire 74 into the position shown in Figure 27J. Guidewire 74 is then withdrawn into the apparatus such that it is proximal to all the catheter curves. Catheter 104 is then again slowly rotated (preferably in the opposite direction from previously) and withdrawn until it flips superiorly into thyrocervical trunk 386, Figure

27L. Slight advancement of catheter 104 thereafter permits entry into the superiorly located anterior-superior RITA arising from right thyrocervical trunk 386.

With the apparatus of the invention positioned as illustrated in Figure 28, angiographic radiopaque contrast 432 is injected into proximal end port 106. This material flows through catheter lumen and exits first through side ports 118 in right innominate and right subclavian, and finally through end port 114 in the distal out of plane segment surrounded by tip 128. This permits complete and simultaneous visualization of the entire innominate 340, subclavian 371, RITA 364, and the associated branches.

Embodied in Figure 29, catheter 104 of the present invention is shown inserted through a percutaneous insertion in the right common femoral artery and following the iliac artery 356, abdominal aorta 354, and thoracic (descending) aorta 352, and into the geriatrically deformed arch of the aorta 338, buckled right innominate 340, and subclavian artery 371. The device is shown selectively inserted into an anterior-inferior located RITA 364. The RCA 326 is totally occluded 360, and RITA 364 has been surgically anastomosed distal to original total occlusion 360. A new or unrecognized pre-operative stenosis 368, beyond RITA-RCA anastomosis is visualized by injection of contrast. Guidewire 74 is then advanced through the catheter shaft into the RITA, the RCA, and across the new stenosis. An apparatus to remove arterial stenosis (such as a PTCA balloon 420, atherectomy device, impregnable chemical, or the like) is advanced over the wire through the RITA and into the new stenosis. The tip 128 of catheter 104 will normally completely occlude blood flow around the catheter into the RITA. Thus, the plurality of side ports 118 provides continuous blood perfusion of the coronary circulation by blood entering side ports 118 in subclavian artery 371 and exiting end port 114 into RITA 364.

Figures 30-32 further depict use of the present invention as hereinabove described.

The invention accordingly consists in the features of the construction, combinations of elements, and construction of parts which will be exemplified in the construction described above and of which the scope of the invention would be indicated in the following claims. It is to be understood that while certain embodiments of the present invention have been illustrated and described, the invention is not to be limited to these specific forms or arrangements of parts herein described and shown.

WHAT IS CLAIMED IS:

1. A catheter for selectively entering and visualizing normal and geriatrically displaced branch vessels of the arch of the aorta and internal thoracic artery origins comprising:

a) a catheter shaft having outer walls defining a central lumen, said outer walls comprising a first portion having a substantially linear shape in an X axis, a second portion extending at an angle toward a Y axis in a curved manner from said first portion and suitable for providing ease of passage for the catheter from a patient's aortic arch into one of the aortic branch vessels and a sub-branch of that vessel, and a third portion extending toward a Z-axis at an out of plane angle relative to said first and second portions and suitable for providing hooked engagement of an internal thoracic artery origin.

2. A catheter according to claim 1 wherein said catheter tip is connected to said catheter shaft at an angle of between $\pm 1°$ and $\pm 179°$ out of plane.

3. A catheter according to claim 1 wherein said catheter tip is connected to said catheter shaft at an angle of between $\pm 30°$ to $\pm 90°$ out of plane.

4. A catheter according to claim 1 wherein the radius of the curve between said outer wall first portion and said outer wall second portion is between 1mm and 25mm.

5. A catheter according to claim 1 wherein the normally curved catheter shaft portions may be substantially straightened by passage of a wire through said central lumen.

6. A catheter for selectively entering and visualizing normal and geriatrically displaced branch vessels of the arch of the aorta and internal thoracic artery origins comprising:

a catheter shaft having outer walls defining a central lumen, said outer walls comprising a first portion having a substantially linear shape, a second portion extending at an angle in a curved manner from said first portion and suitable for providing ease of passage for the catheter from a patient's aortic arch into one of the aortic branch vessels and a sub-branch of that vessel, said first and second portions defining an X-Y plane, and a third portion extending at an out of plane angle, said third portion presenting a Z-axis component relative to the X-Y plane defined by said first and second portions, said third portion being configured for providing hooked engagement of an internal thoracic artery origin.

7. A catheter according to claim 6 wherein said catheter tip is connected to said catheter shaft at an angle of between $\pm$ 1° and $\pm$ 179° out of plane.

8. A catheter according to claim 6 wherein the radius of the curve between said outer wall first portion and said outer wall second portion is between 1mm and 25mm.

9. A catheter according to claim 6 wherein the normally curved catheter shaft portions may be substantially straightened by passage of a wire through said central lumen.

10. A catheter according to claim 6 wherein said catheter tip comprises a soft deformable and radiopaque tip having a central aperture.

11. A catheter according to claim 6 wherein the angle between said first and second portions is between 1° and 364°.

12. A catheter according to claim 6 wherein said out of plane angle between said second and third portion is between 1° and 179°.

13. A catheter according to claim 6 wherein said aortic branch comprises an arterial bypass graft.

14. A catheter according to claim 6 wherein the out of plane angle of said third portion and the out of plane angle of said catheter tip are constructed and arranged so that said catheter may be rotated within a subclavian artery to selectively engage the origin of an internal thoracic artery independent of the congenitally determined location and shape of the internal thoracic artery origin.

15. A method for selectively entering a branch artery of an aorta with apparati for removing vascular obstruction within an artery, comprising the steps of:

a) percutaneously inserting a guidewire into a femoral artery;

b) advancing the guidewire under fluoroscopic control into the aorta;

c) threading a preformed pliable catheter comprising a selectively out of plane distal tip portion over the guidewire to a position within the aorta;

d) withdrawing the guidewire into the catheter to permit the catheter to resume a preformed shape;

e) selectively rotating and withdrawing the catheter proximally until the out of plane distal tip portion hooks a normal or geriatrically displaced left subclavian artery origin;

f) secondarily advancing the guidewire distally into the left subclavian artery to a position past the origin of the left internal thoracic artery;

g) secondarily withdrawing the guidewire into the catheter proximally to again permit the catheter to resume a preformed shape; and

h) secondarily rotating and slowly withdrawing the catheter to permit the out of plane distal tip portion to hook and enter a left internal thoracic artery.

16. A method according to claim 15 further comprising the steps of:

a) repositioning the guidewire distally within the left subclavian artery;

b) thirdly advancing the catheter distally over the guidewire;

c) thirdly withdrawing the guidewire into the catheter to again permit the catheter to resume a preformed shape;

d) thirdly rotating and slowly withdrawing the catheter proximally to permit the out of plane distal tip portion to hook and enter the left thyrocervical trunk; and

e) slightly advancting the catheter along the guidewire to permit entry of the catheter into the alternately located left internal thoracic artery.

17. The method according to claims 15 or 16, further comprising the step of proximally injecting angiographic radiopaque contrast material into the catheter so that the contrast material exits the catheter in both the left subclavian artery and the left internal thoracic artery to permit simultaneous visualization of the left subclavian artery, the left internal thoracic artery, branches of the left internal thoracic artery, and bypass graft systems utilizing the left internal thoracic artery.

18. A method for selectively entering a branch artery of an aorta with apparati for removing vascular obstruction within an artery, comprising the steps of:

a) percutaneously inserting a guidewire into a femoral artery;

b) advancing the guidewire under fluoroscopic control into the ascending aorta;

c) threading a preformed pliable catheter comprising a selectively out of plane distal tip portion over the guidewire to a position past the right innominate artery origin into the ascending aorta;

d) withdrawing the guidewire into the catheter to permit the catheter to resume a preformed shape;

e) selectively rotating and withdrawing the catheter proximally until the out of plane distal tip portion hooks a normal or geriatrically displaced right innominate artery origin;

f) secondarily advancing the guidewire distally until it enters the right innominate artery and the right subclavian artery to a position past the origin of the right internal thoracic artery;

g) secondarily withdrawing the guidewire into the catheter to again permit the catheter to resume a preformed shape; and

h) secondarily rotating and slowly withdrawing the catheter to permit the out of plane distal tip portion to hook and enter the right internal thoracic artery.

19. A method according to claim 18 further comprising the steps of:

a) repositioning the guidewire distally within the right subclavian artery;

b) thirdly advancing the catheter distally over the guidewire;

c) thirdly withdrawing the guidewire into the catheter to again permit the catheter to resume a preformed shape;

d) thirdly rotating and slowly withdrawing the catheter to permit the out of plane distal tip portion to hook and enter the right thyrocervical trunk; and

e) slightly advancing the catheter along the guidewire to permit entry of the catheter into the alternately located right internal thoracic artery.

20. The method according to claims 18 or 19, further comprising the step of proximally injecting angiographic radiopaque contrast material into the catheter so that the contrast material exits the catheter in both the right subclavian artery and the right internal thoracic artery to permit simultaneous visualization of the right subclavian innominate artery, the right internal thoracic artery, branches of the right internal thoracic artery, and bypass graft systems utilizing the right internal thoracic artery.

Fig. 1

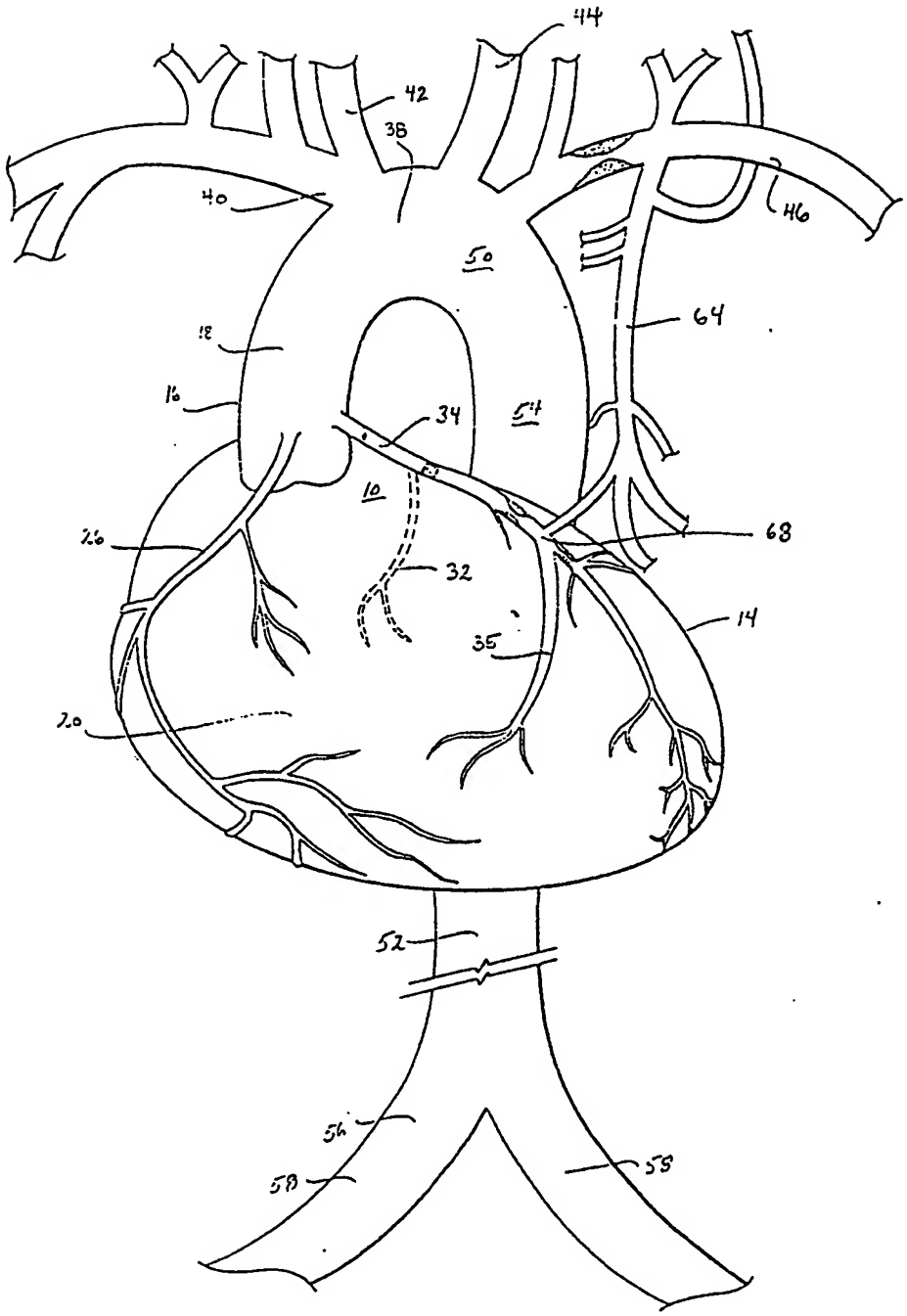


Fig. 2A

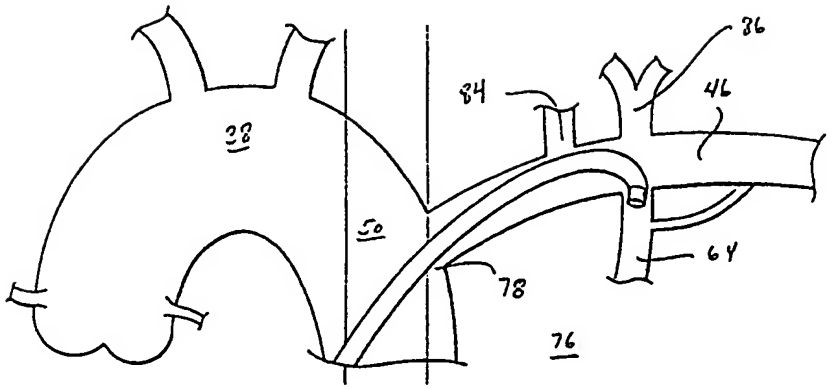


Fig. 2B

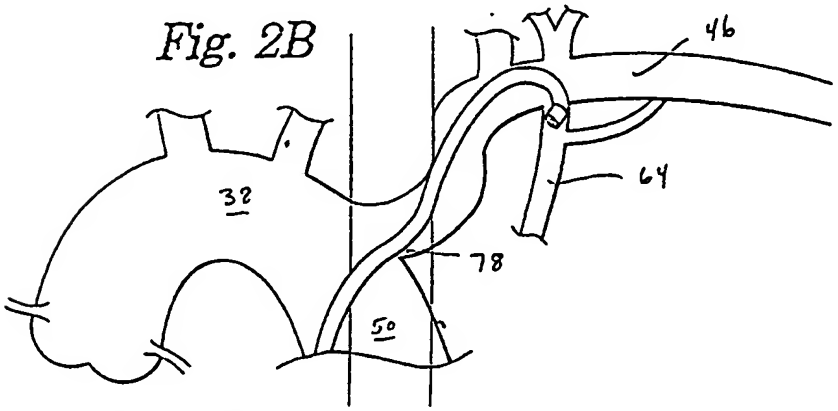


Fig. 2C

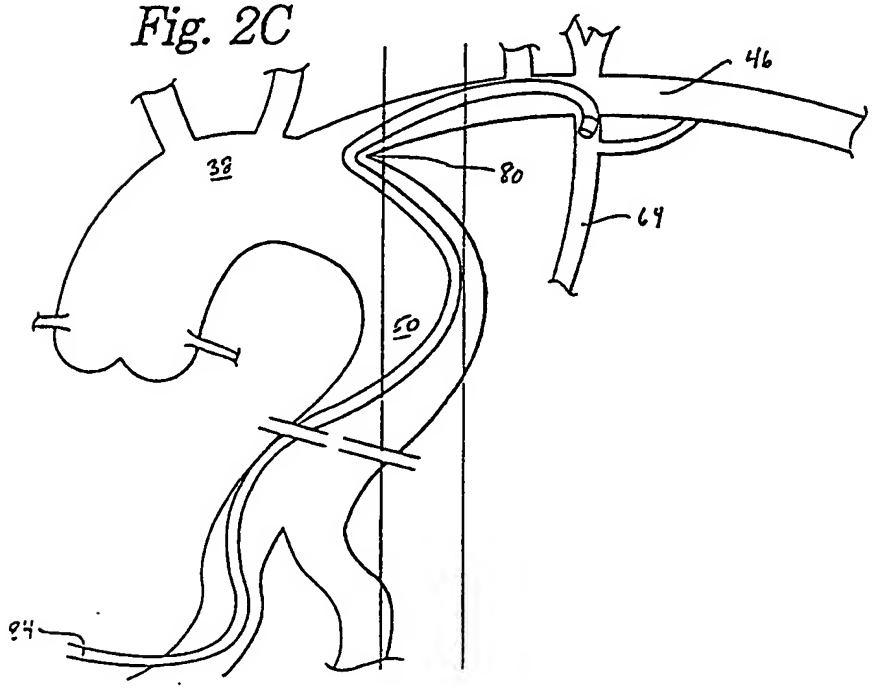


Fig. 3A

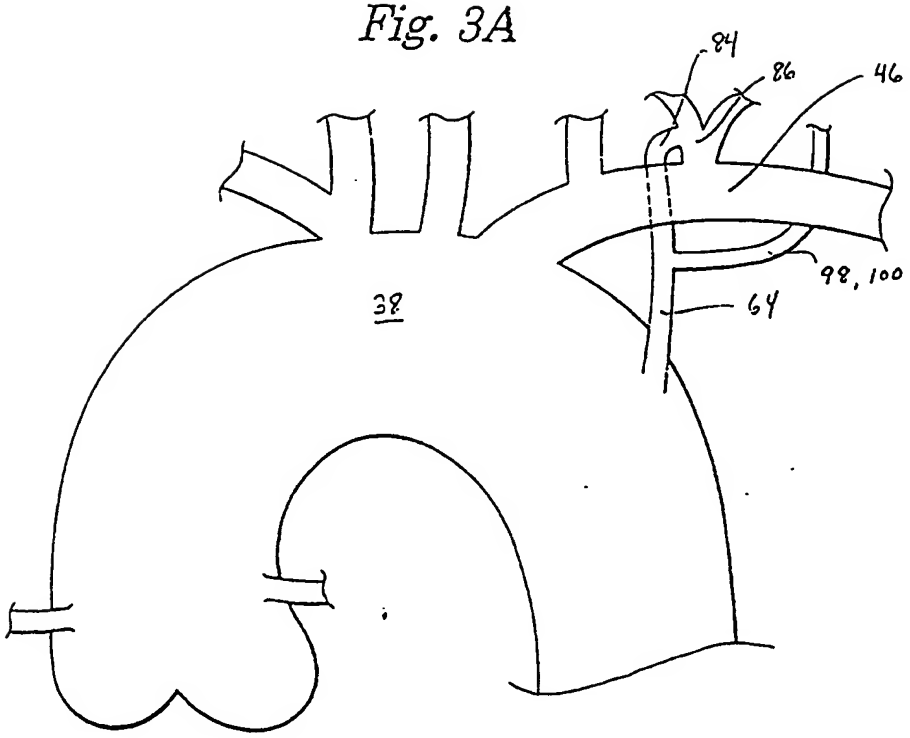


Fig. 3B

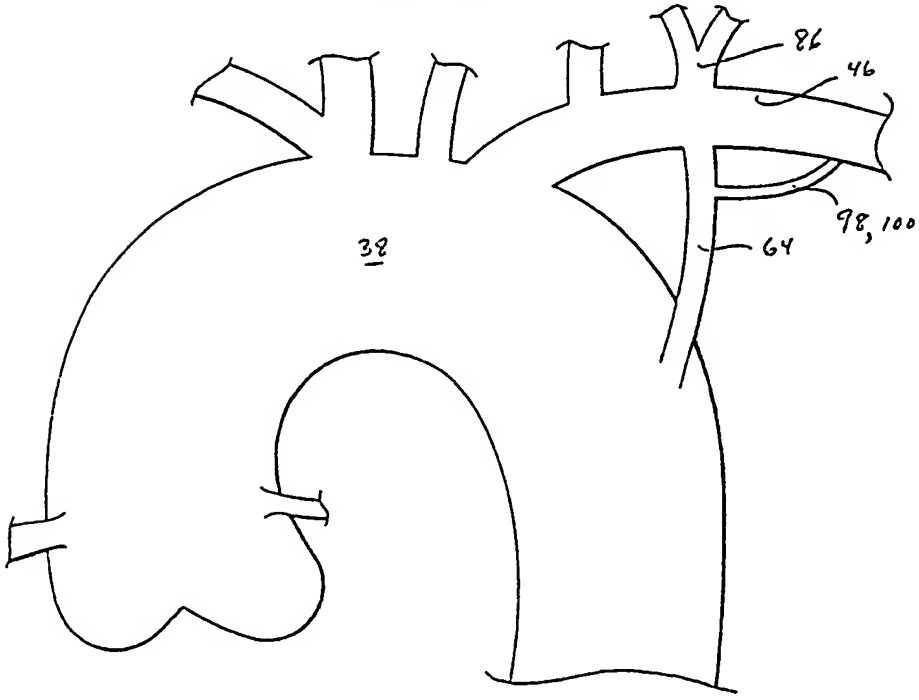


Fig. 4A

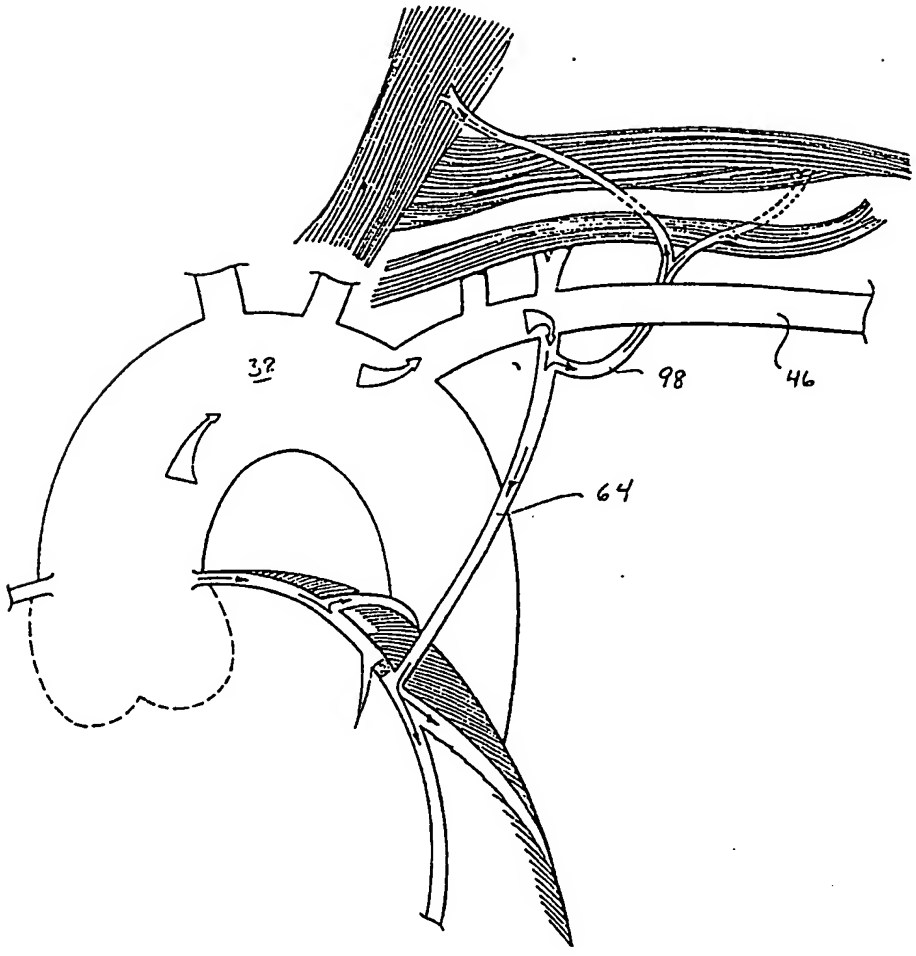


Fig. 4B

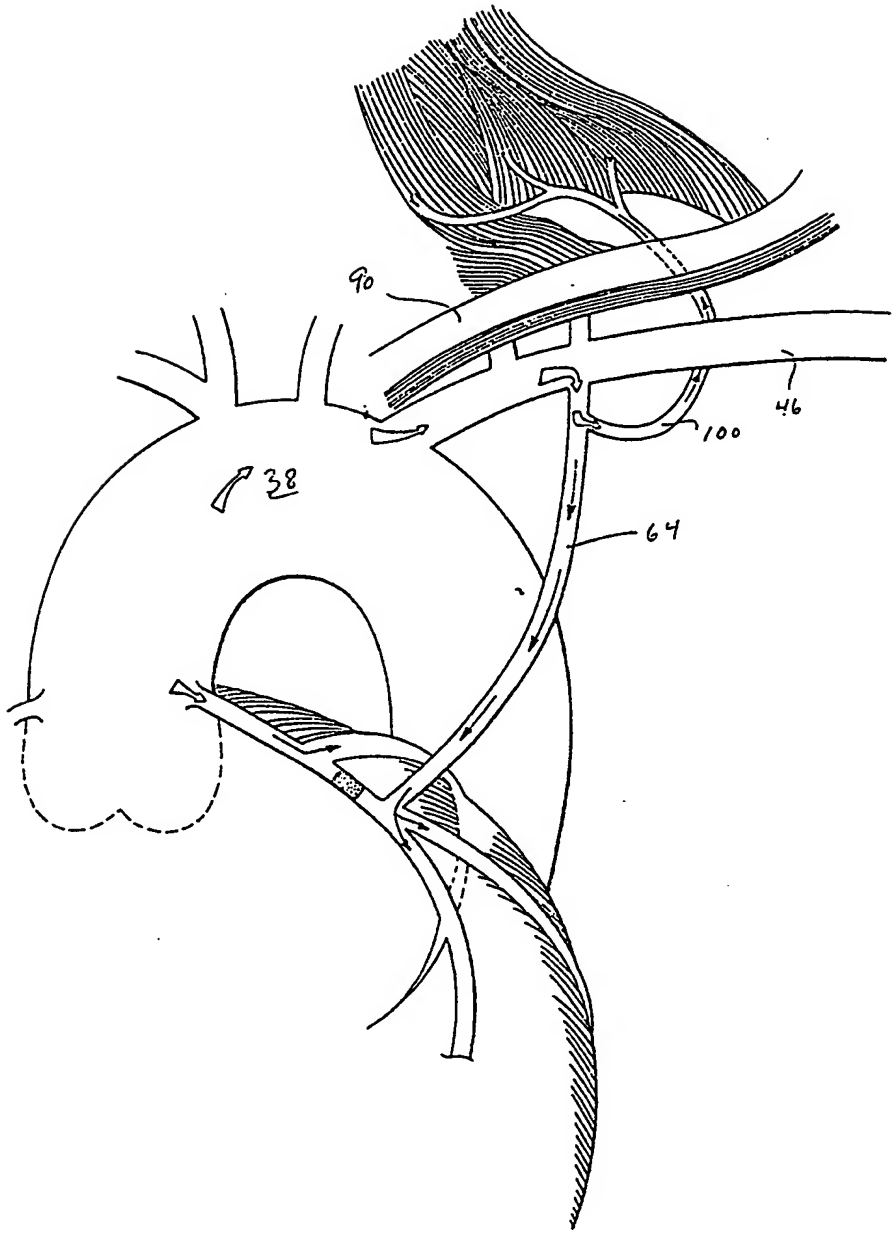


Fig. 5

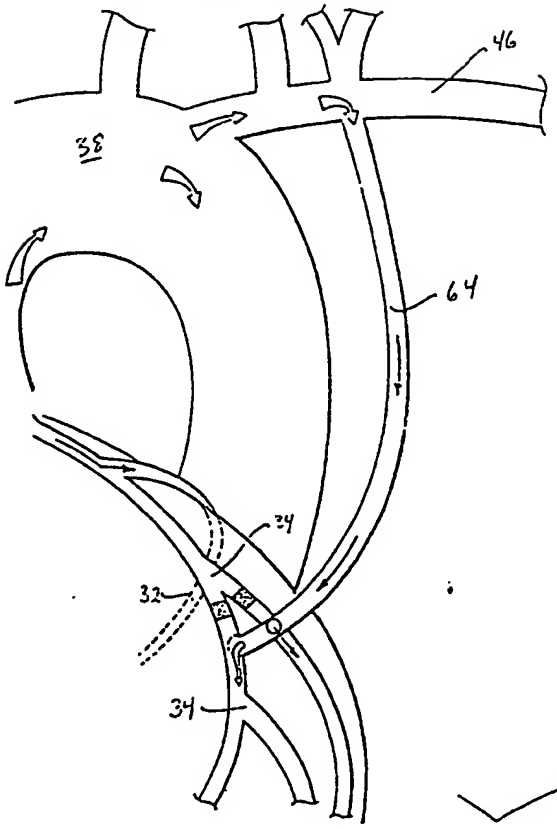


Fig. 6

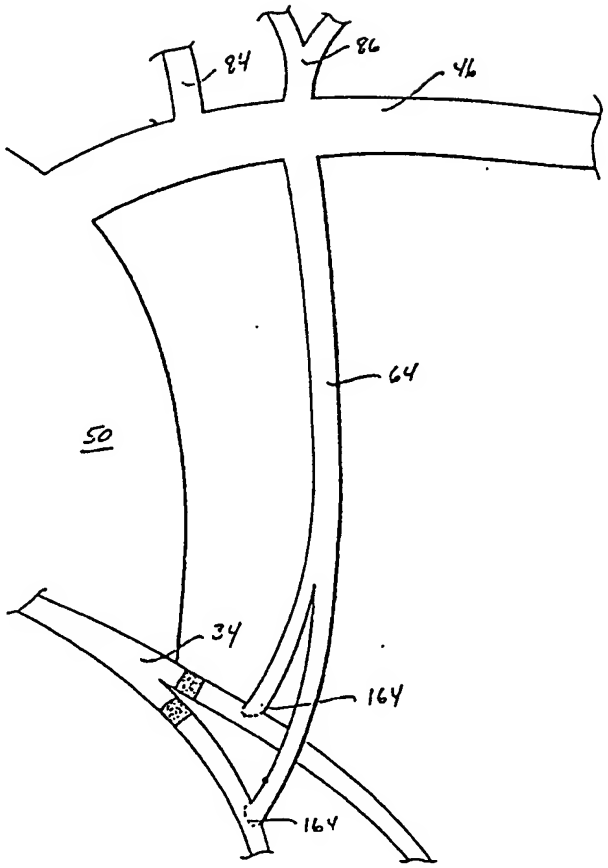


Fig. 7A

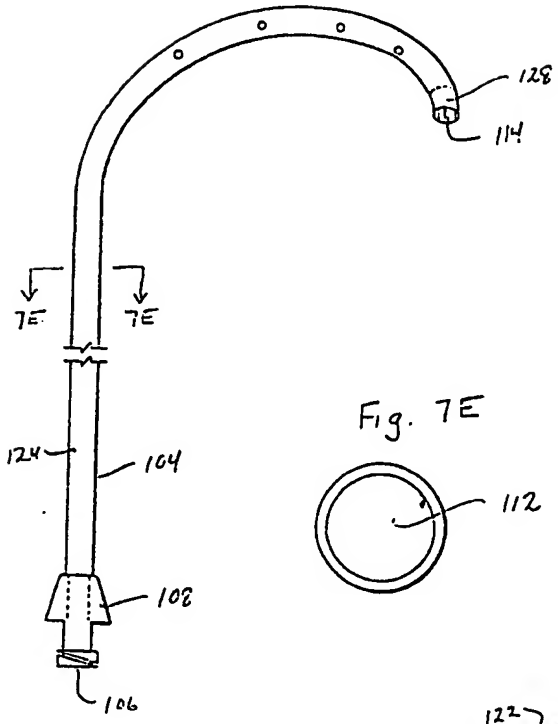
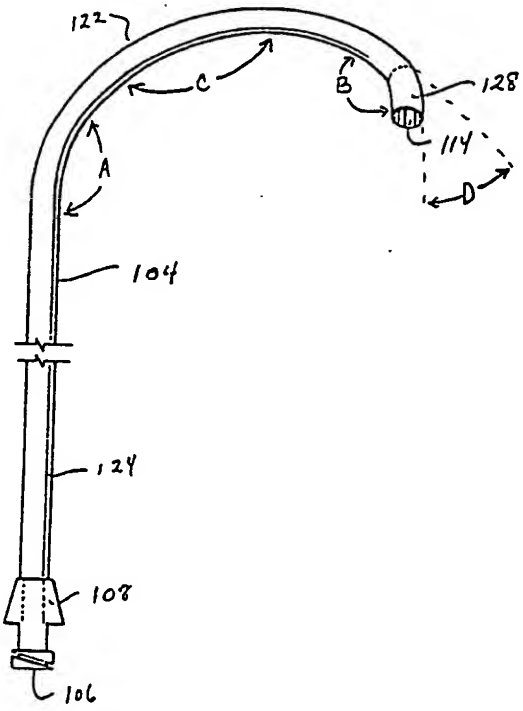


Fig. 7E

Fig. 7B



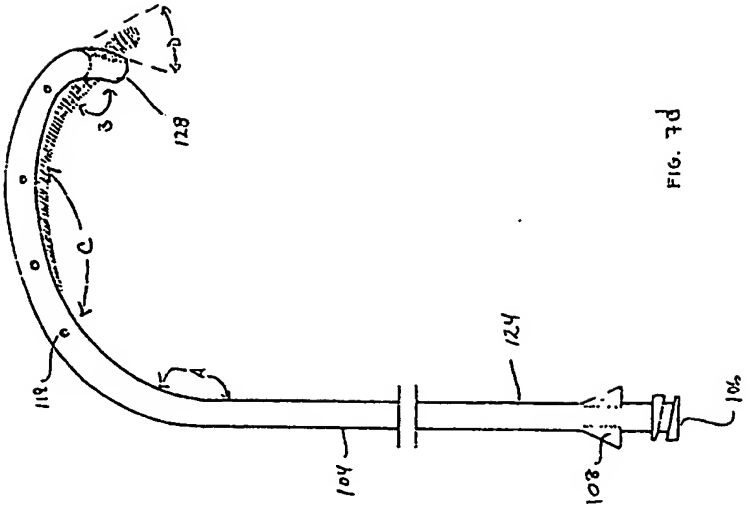


FIG. 7d

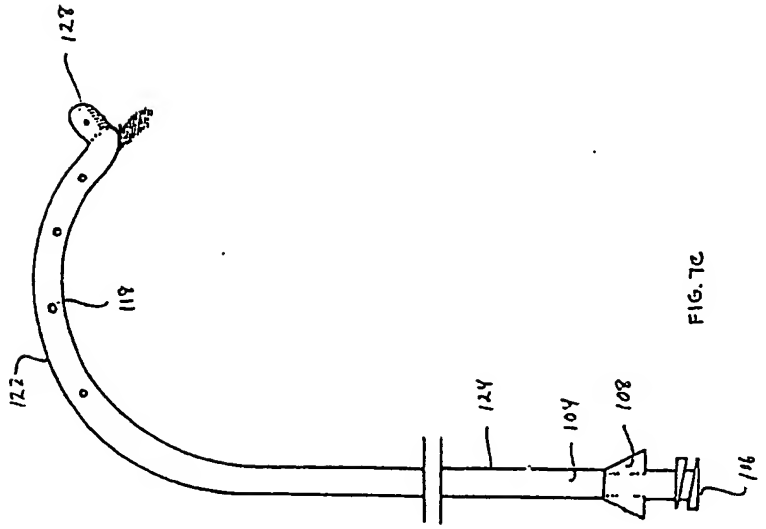


FIG. 7c

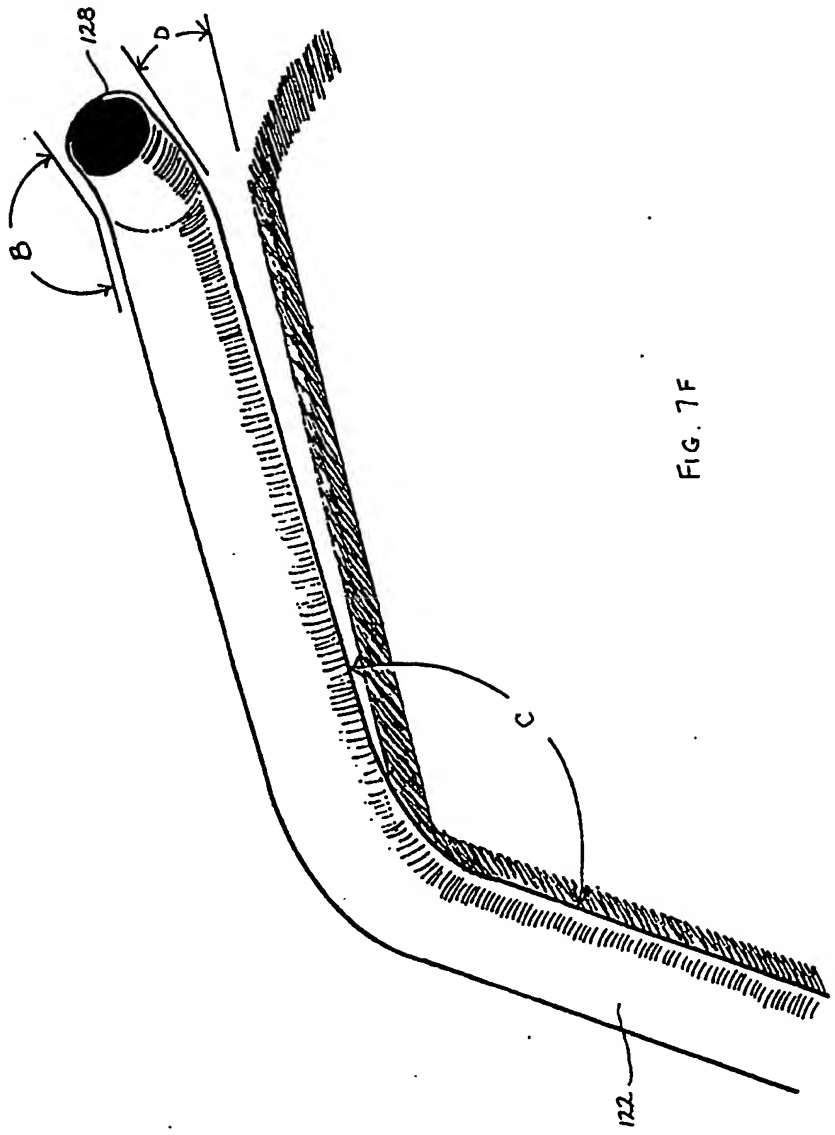


FIG. 7F

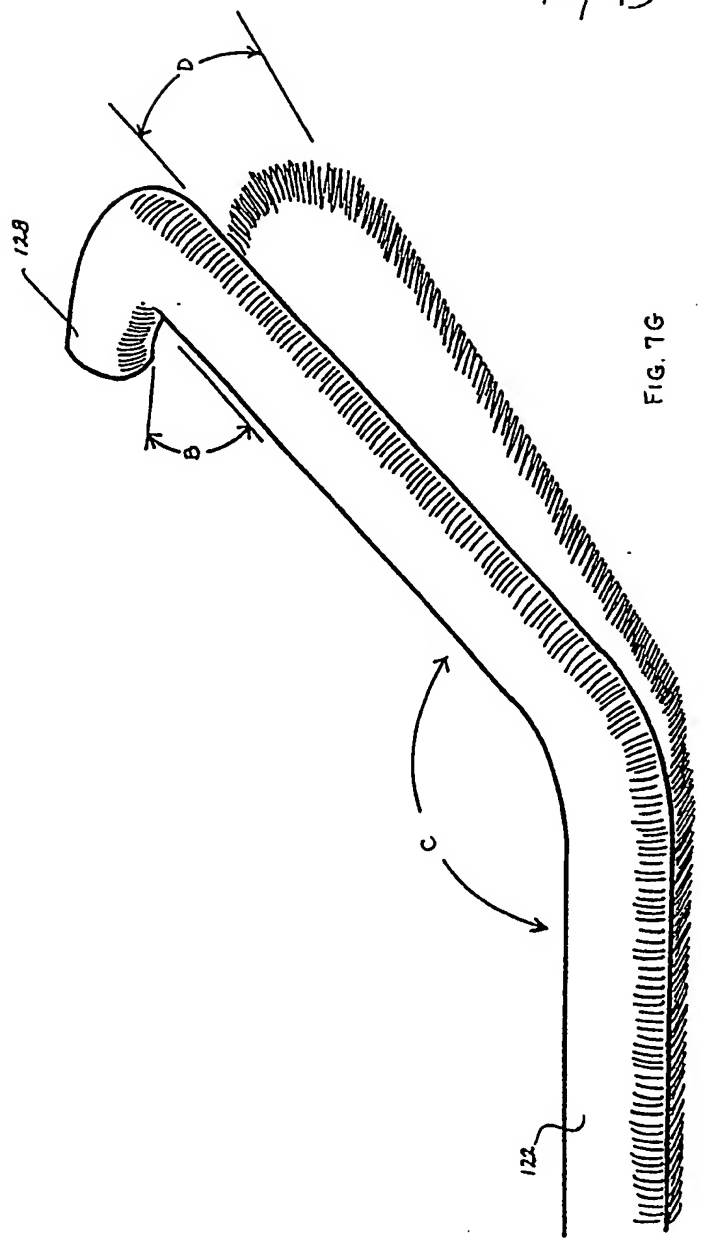


FIG. 7G

Fig. 8A

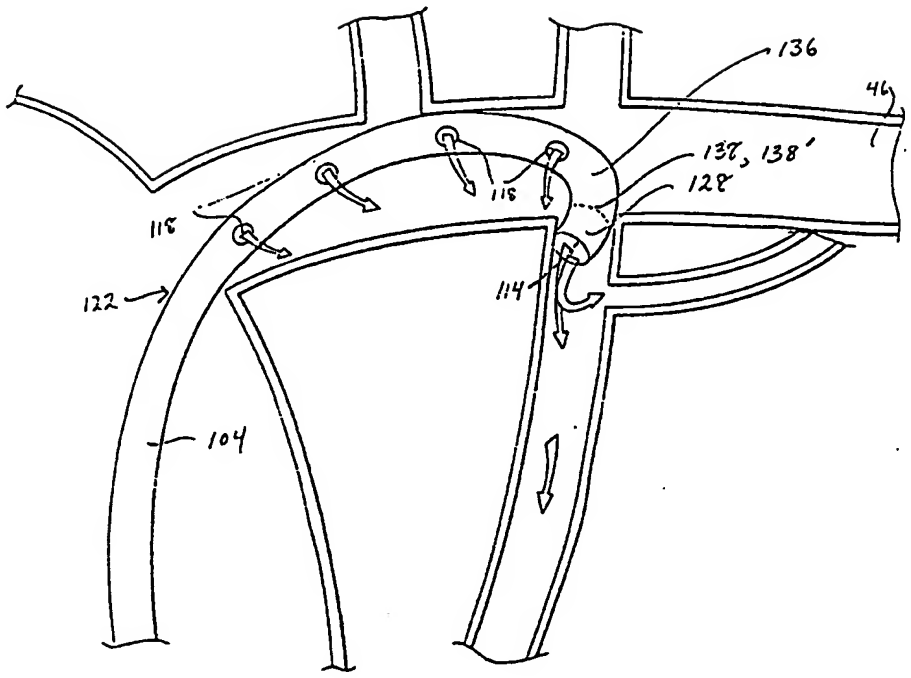


Fig. 8B

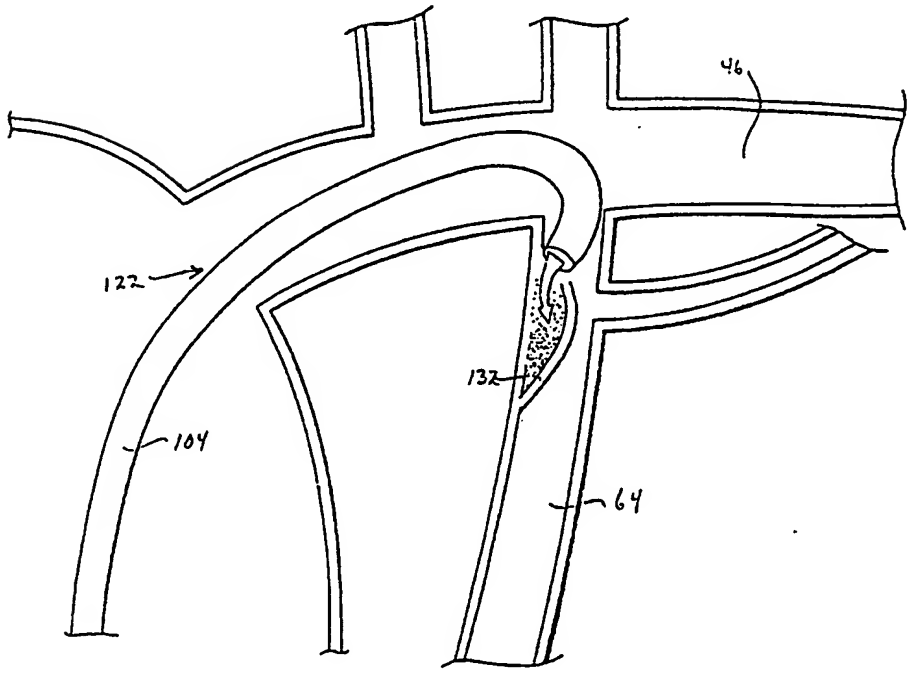


Fig. 8C

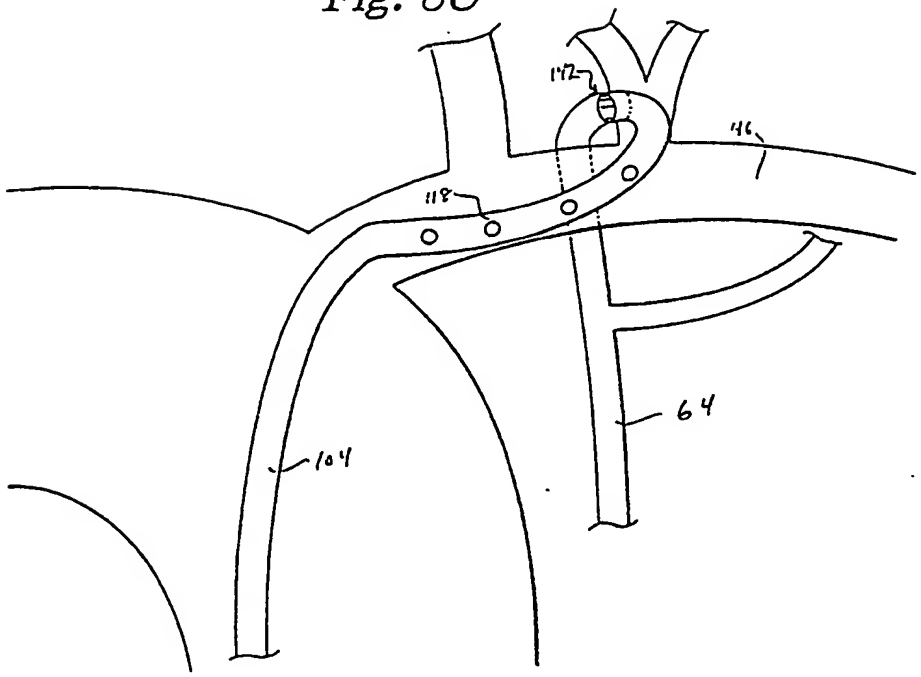


Fig. 8D

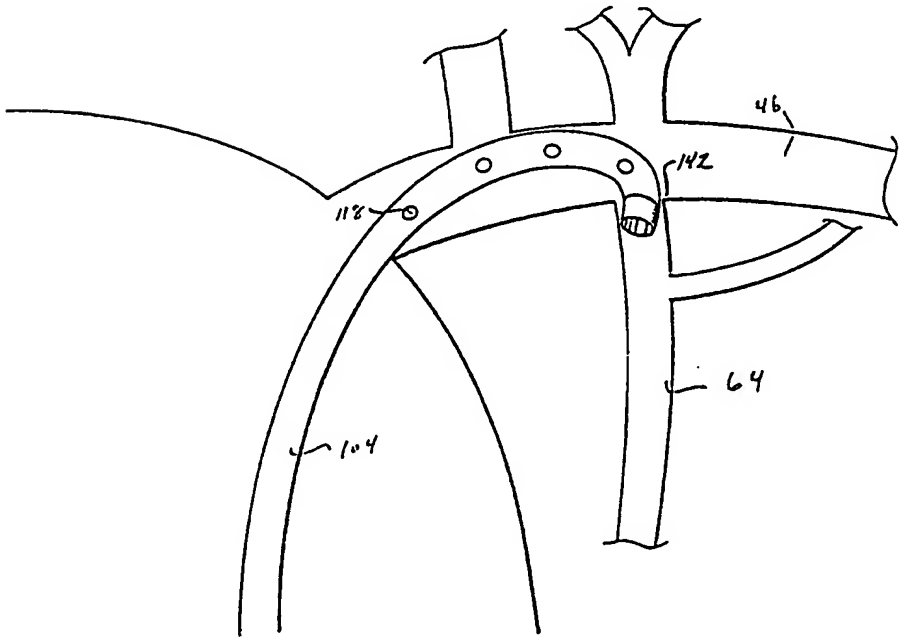


Fig. 9

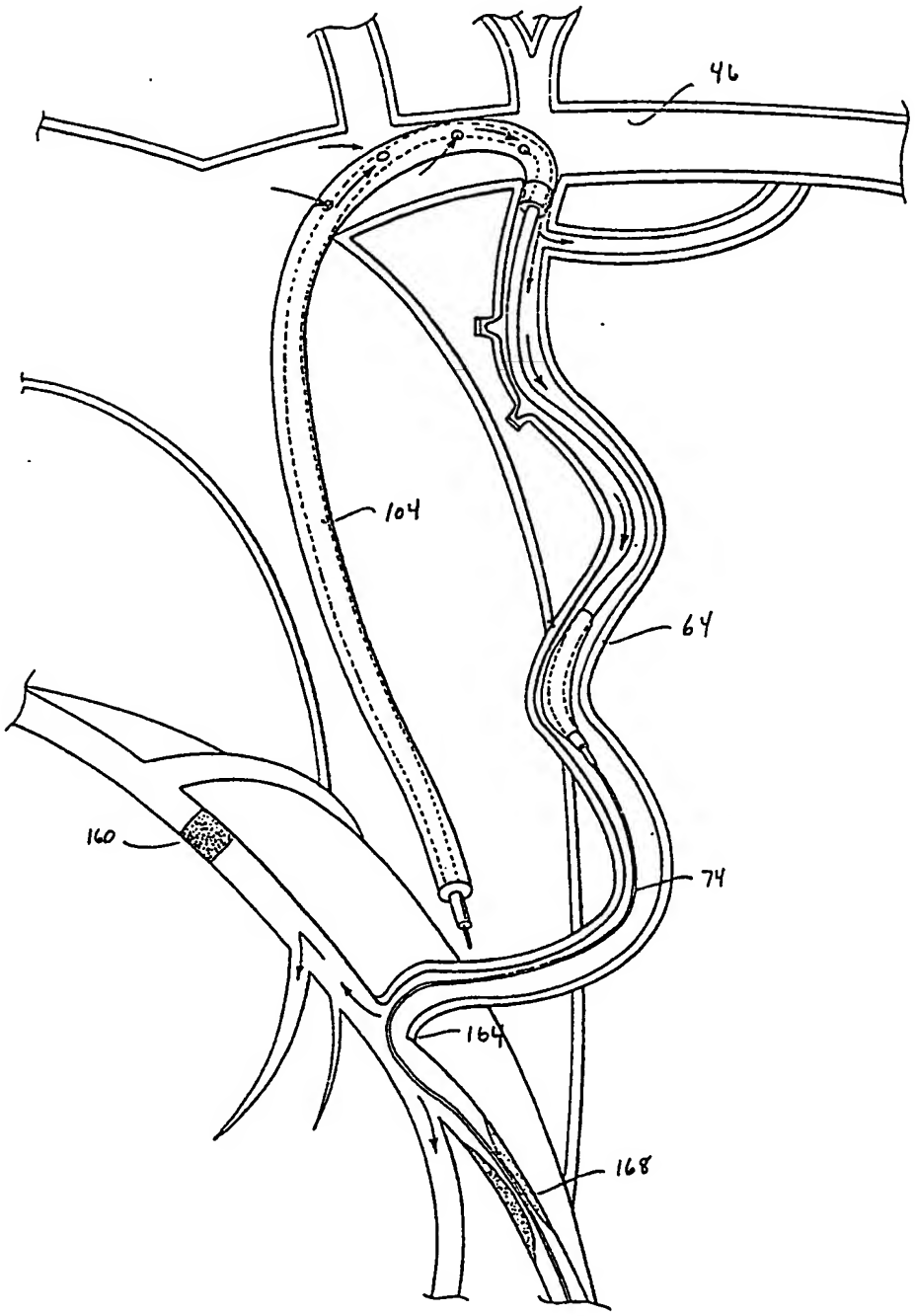


Fig. 10A

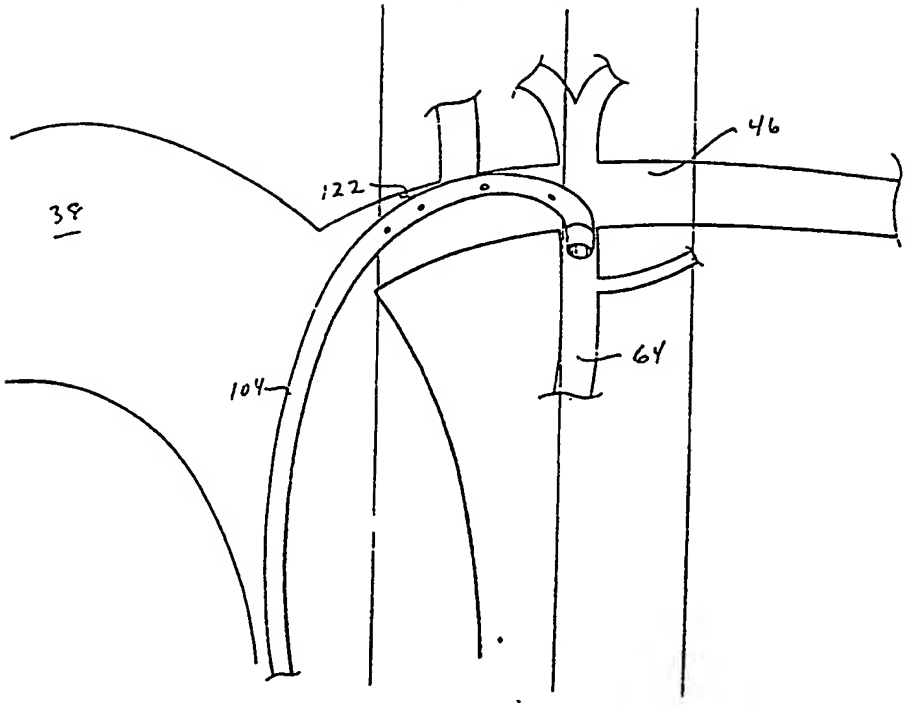


Fig. 10B

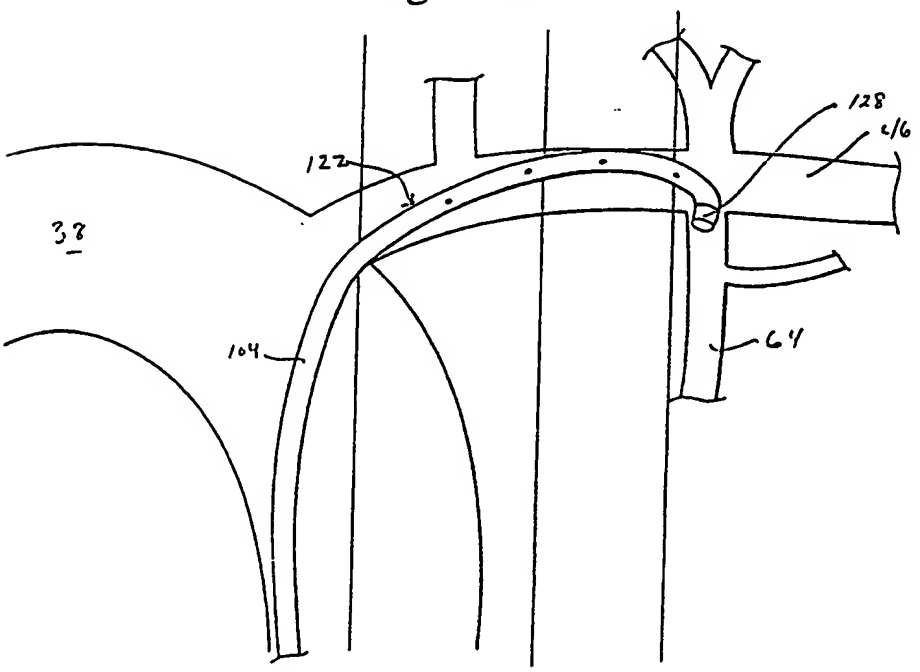


Fig. 11A

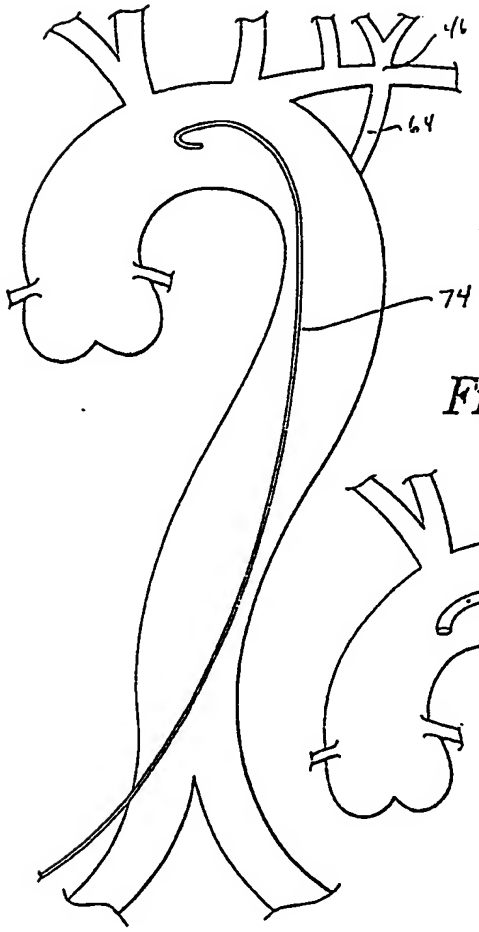


Fig. 11B

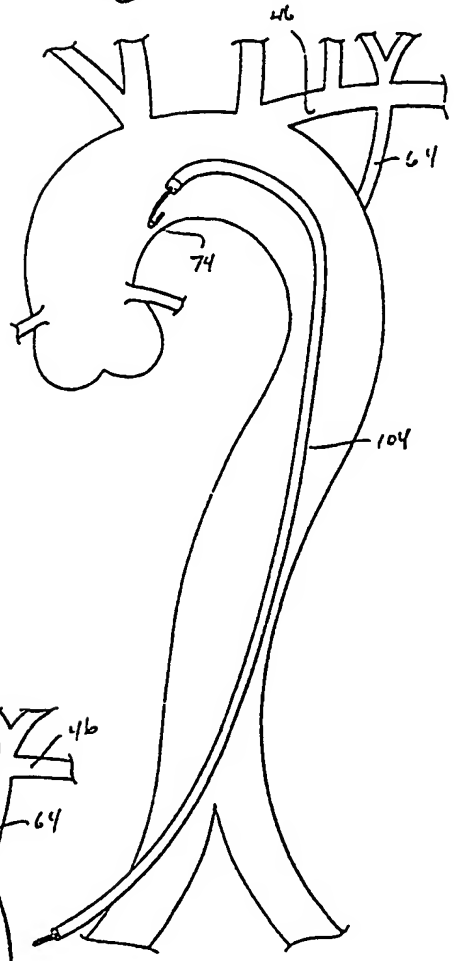


Fig. 11C

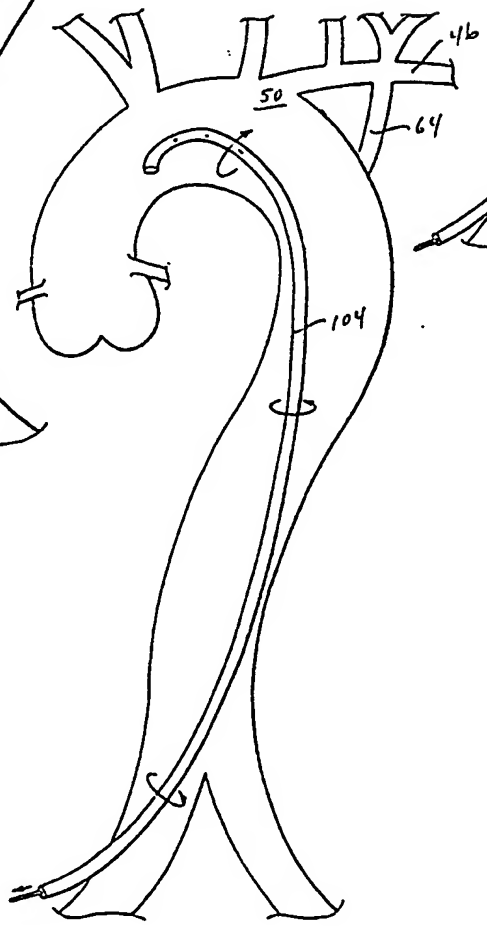


Fig. 11D

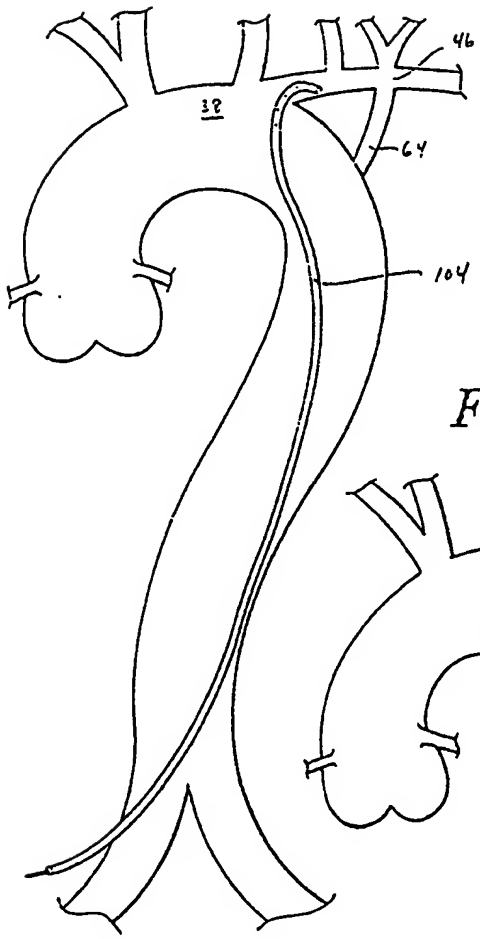


Fig. 11E

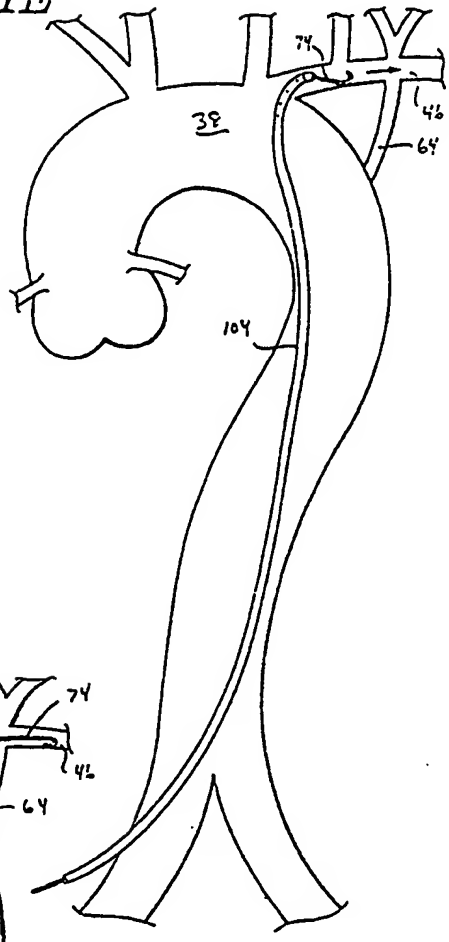


Fig. 11F

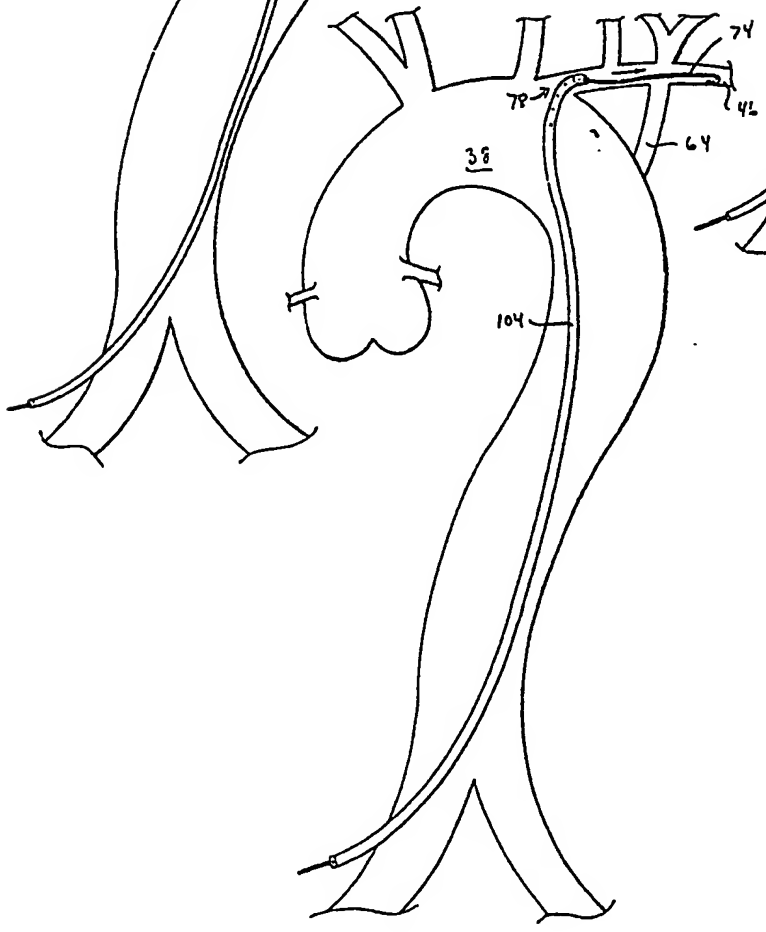


Fig. 11H

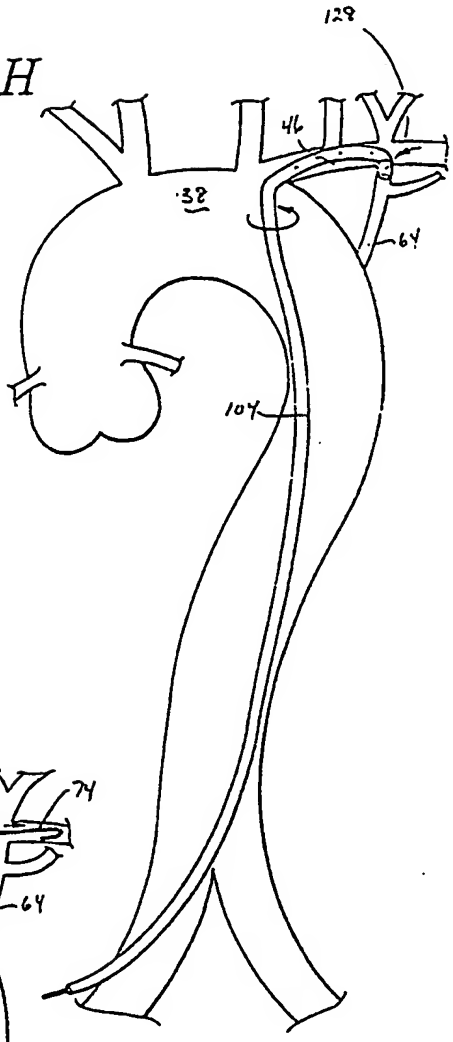


Fig. 11G

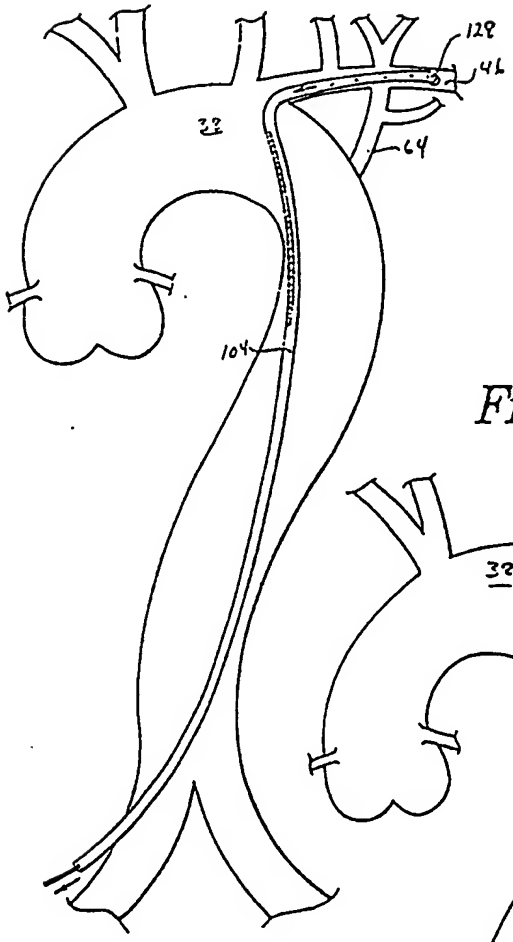


Fig. 11I

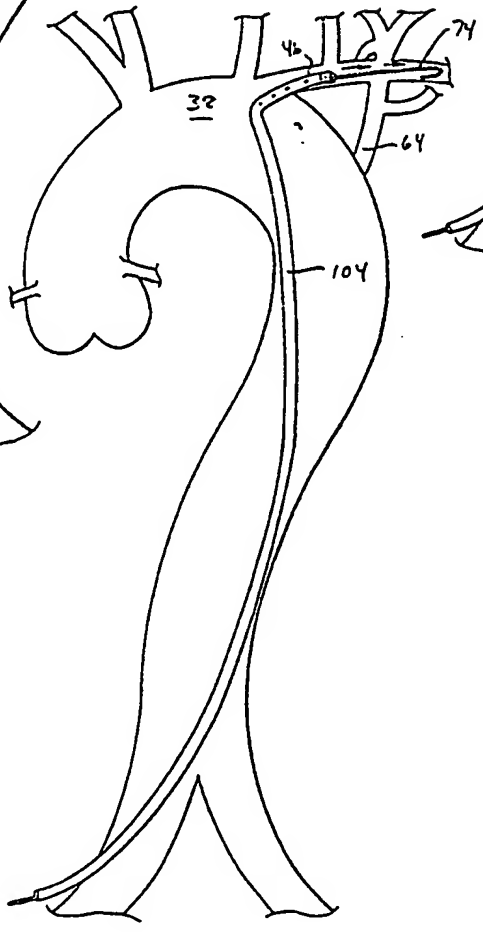


Fig. 11K

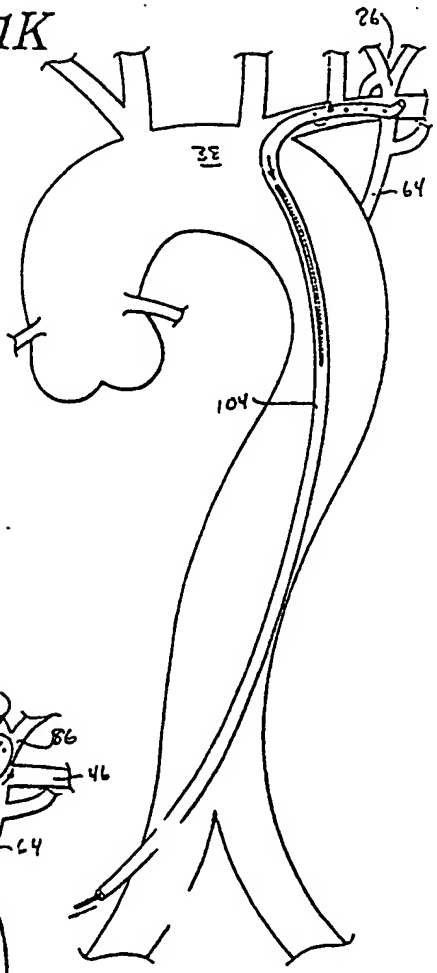


Fig. 11J

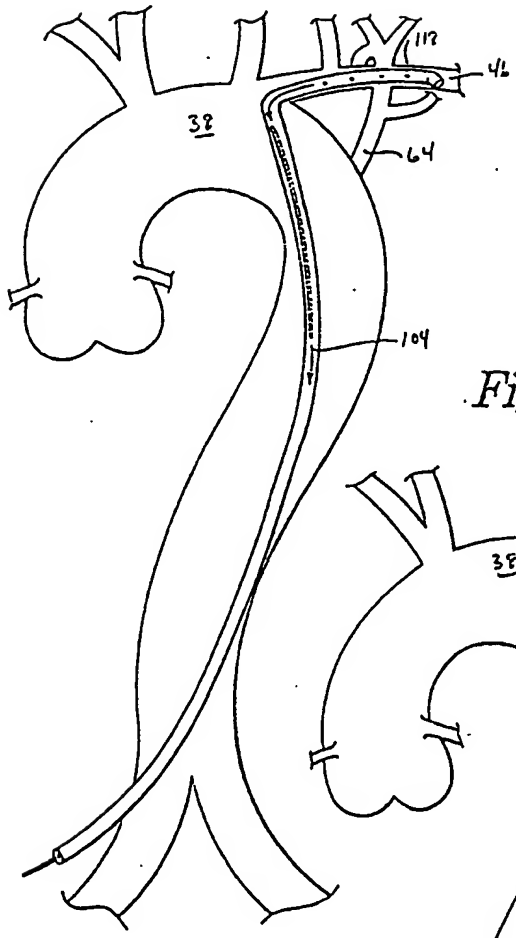


Fig. 11L

Fig. 12

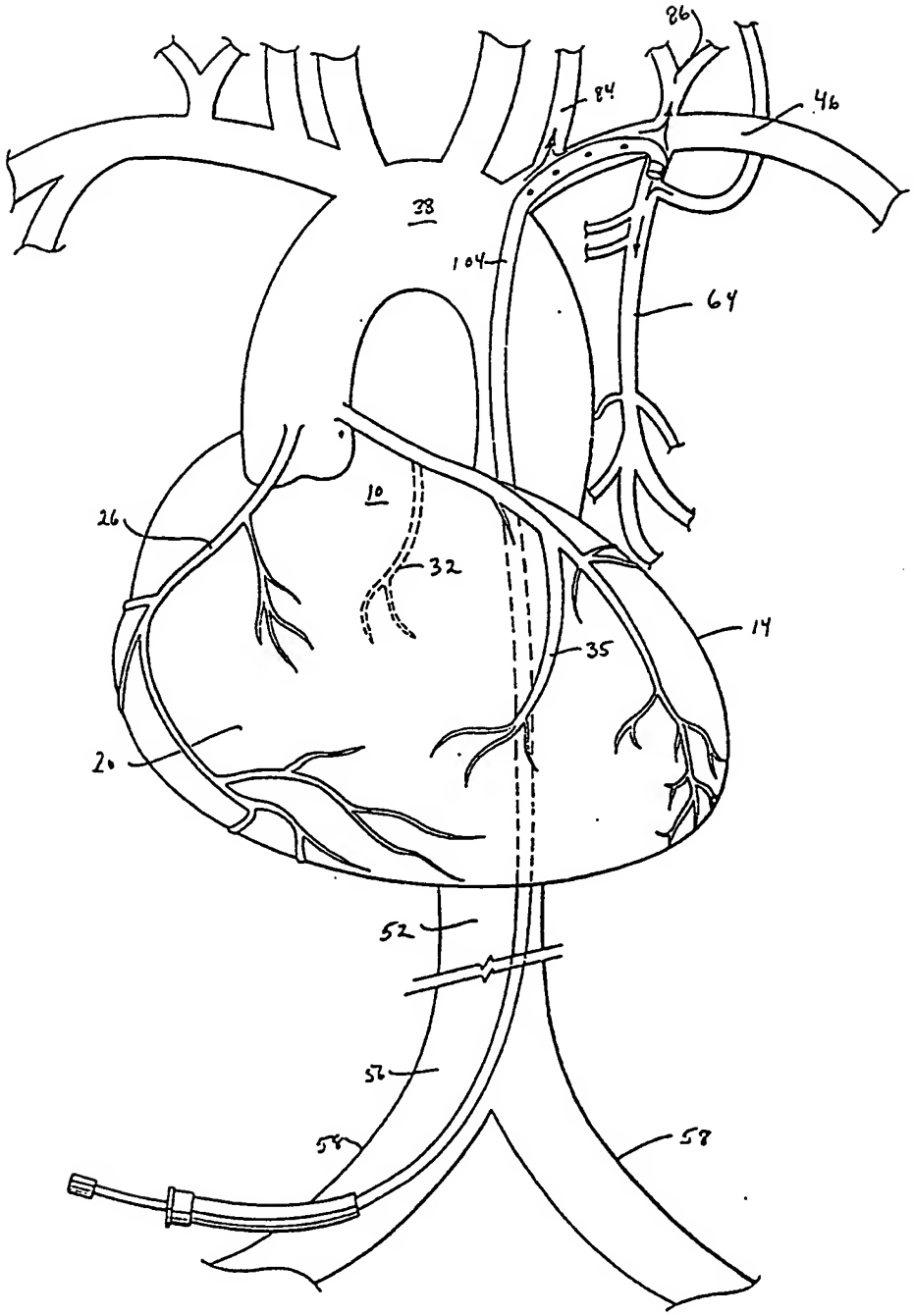


Fig. 13

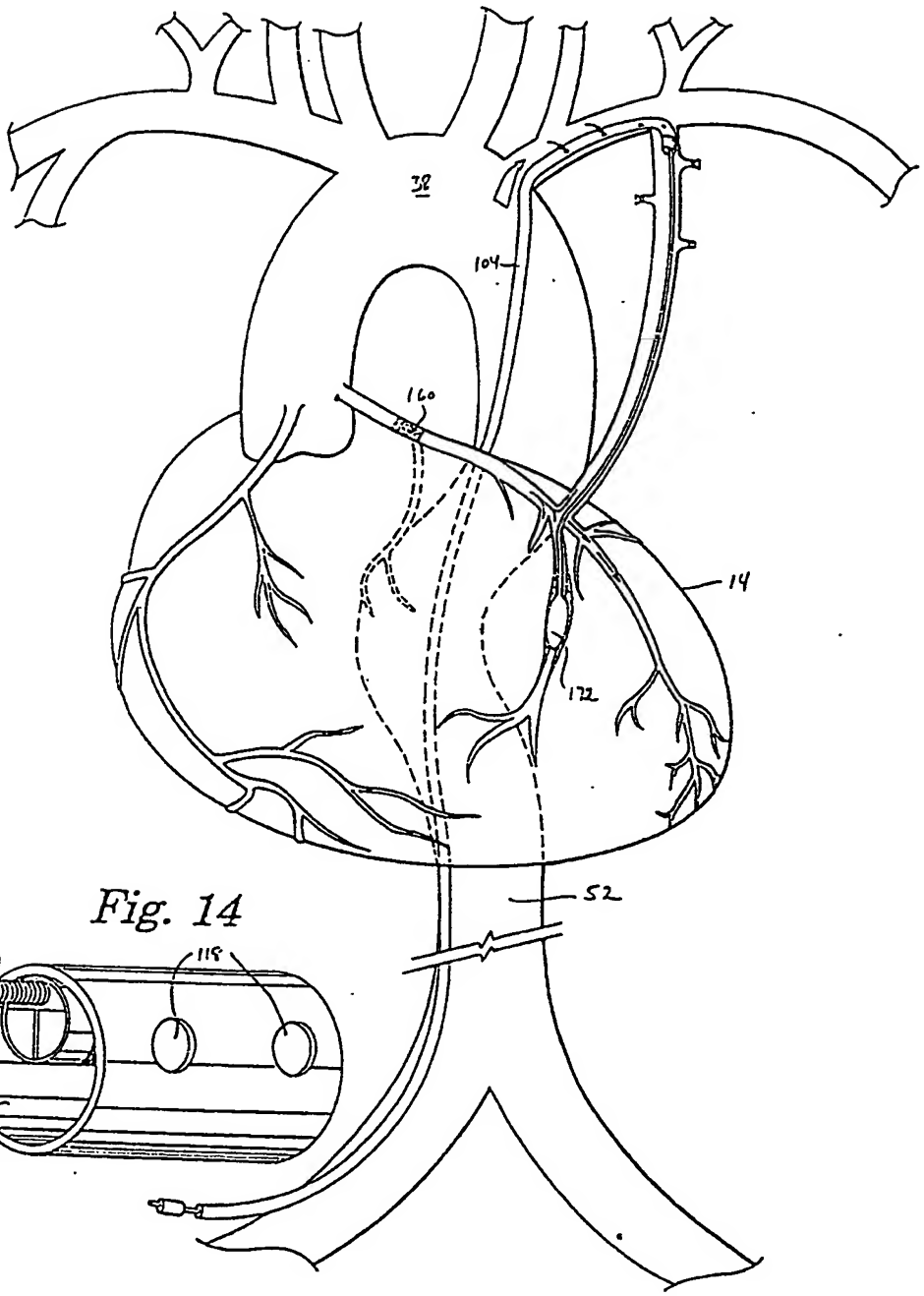


Fig. 14

Fig. 15

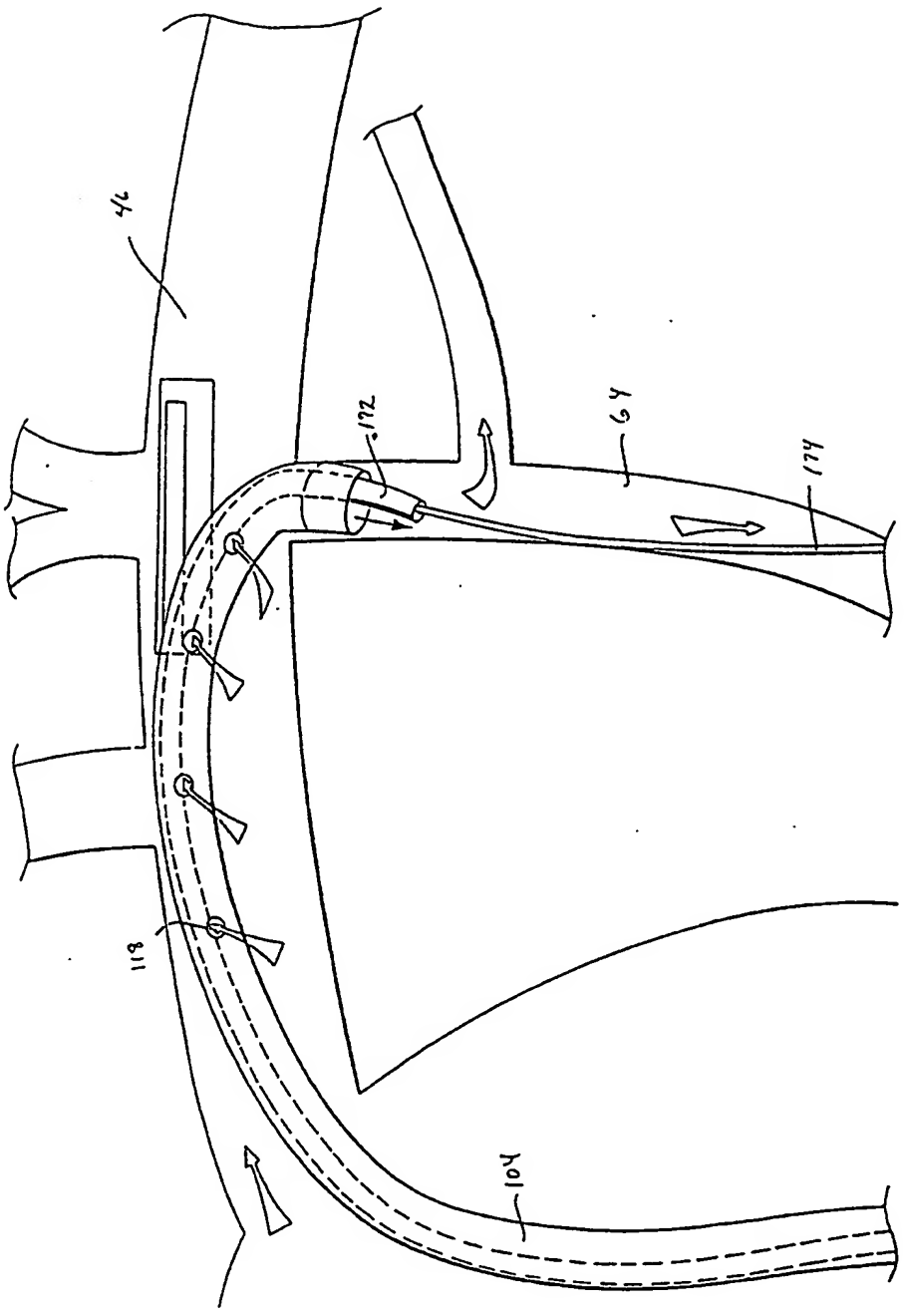


Fig. 16

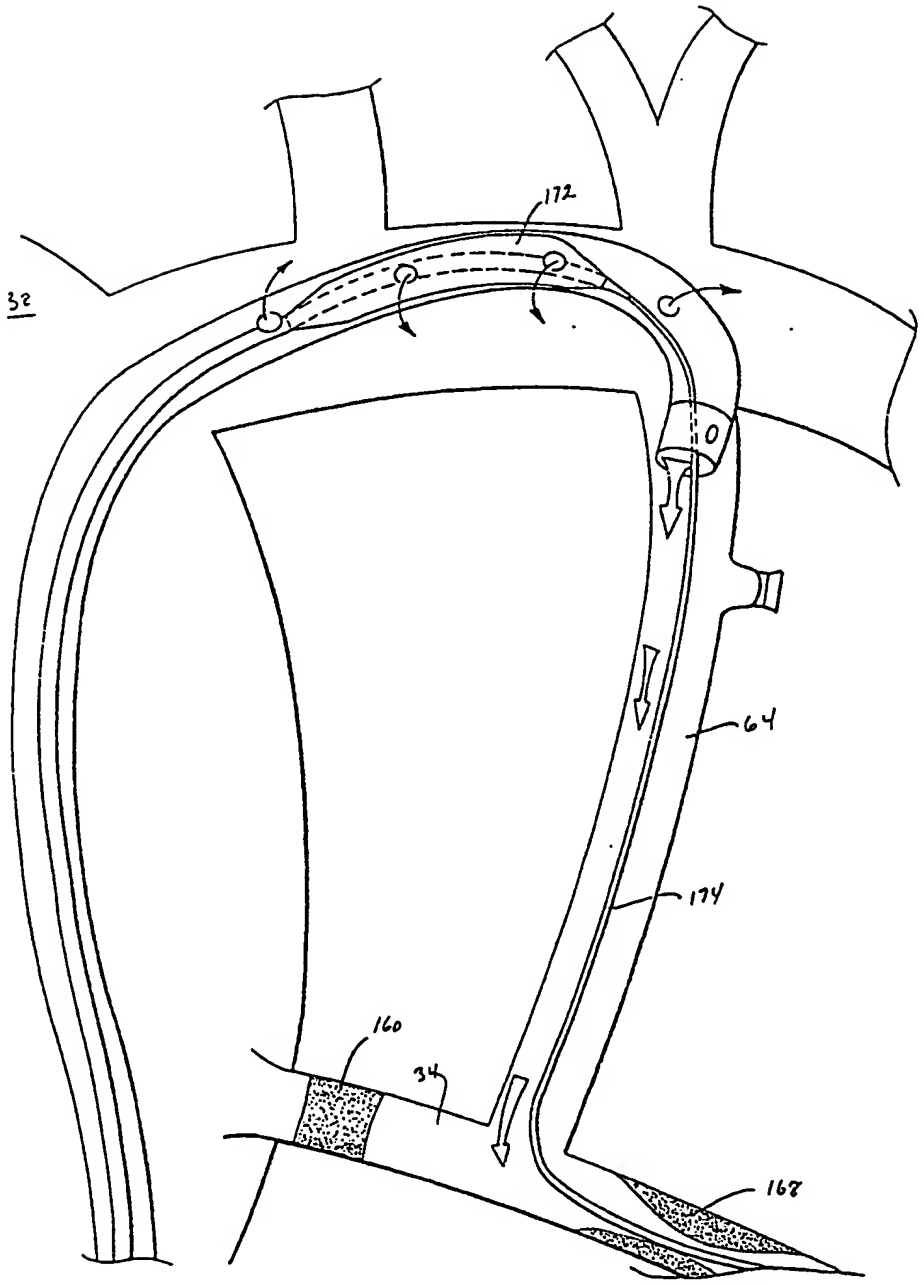
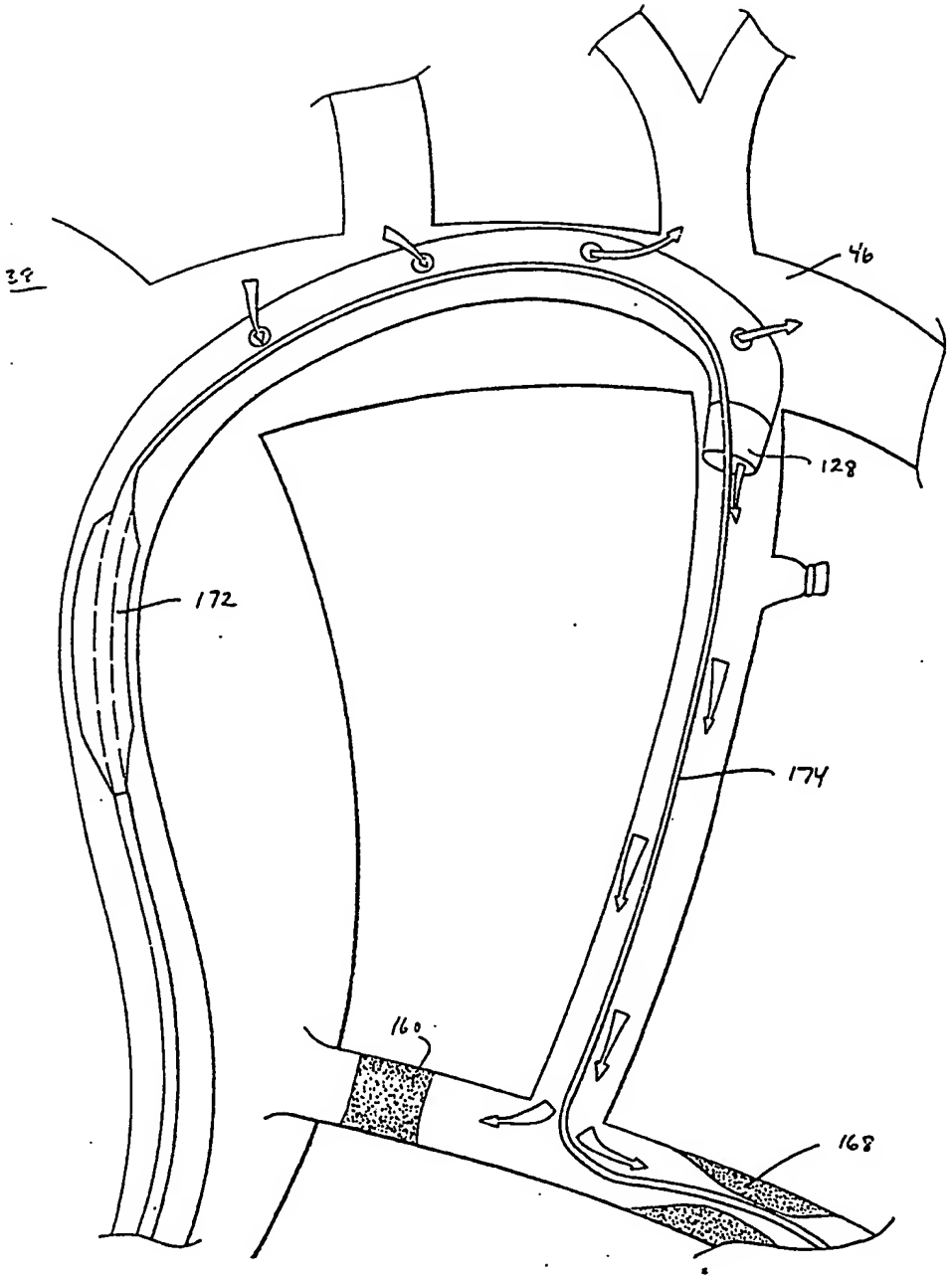


Fig. 17



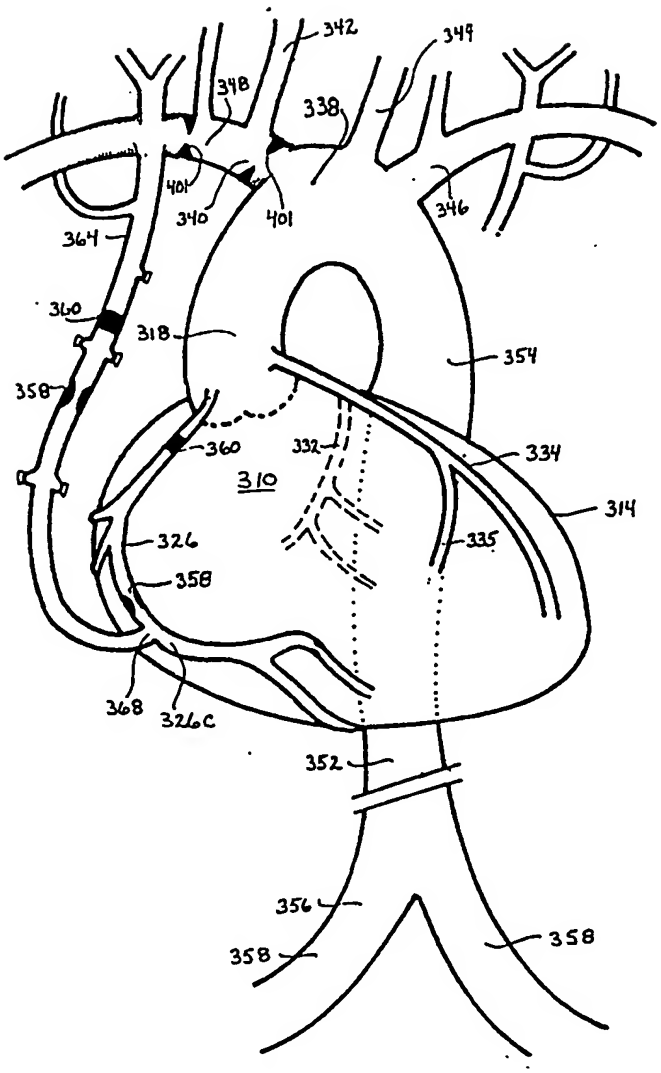

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FIG. 18

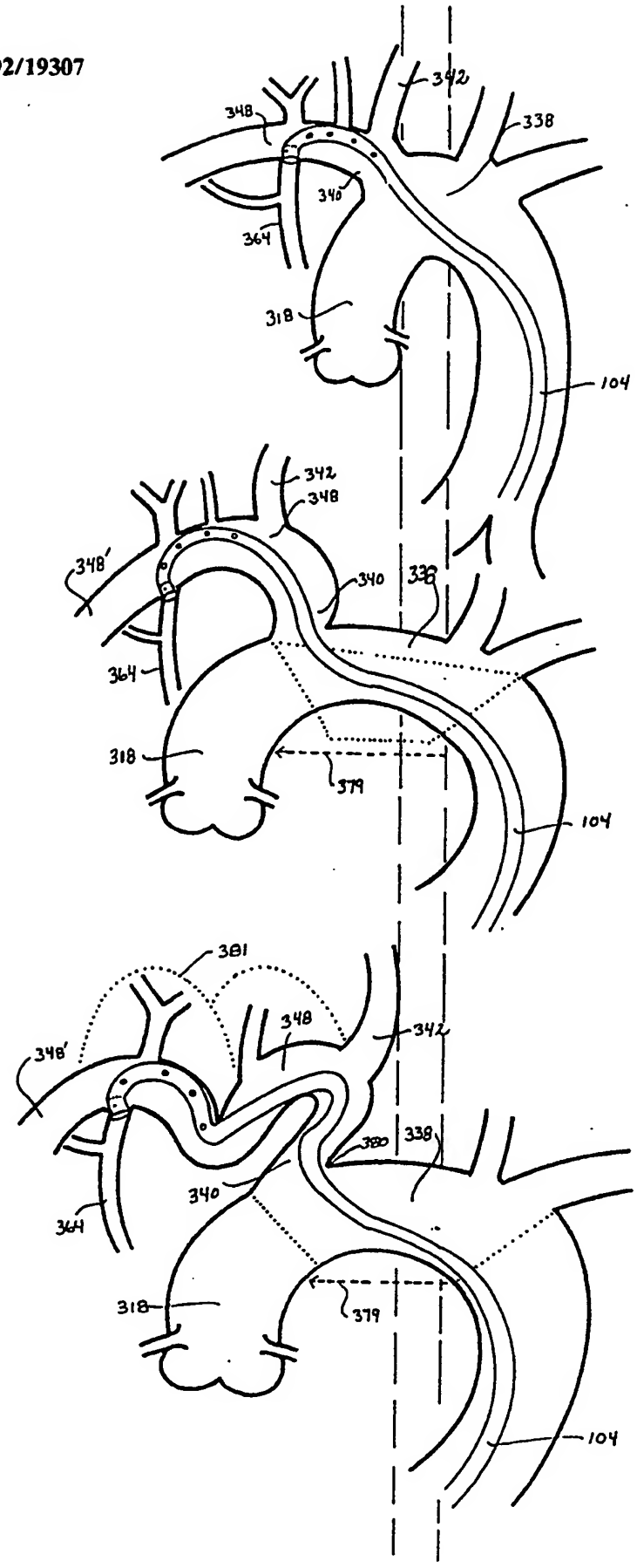


FIG. 19A

FIG. 19B

FIG. 19C

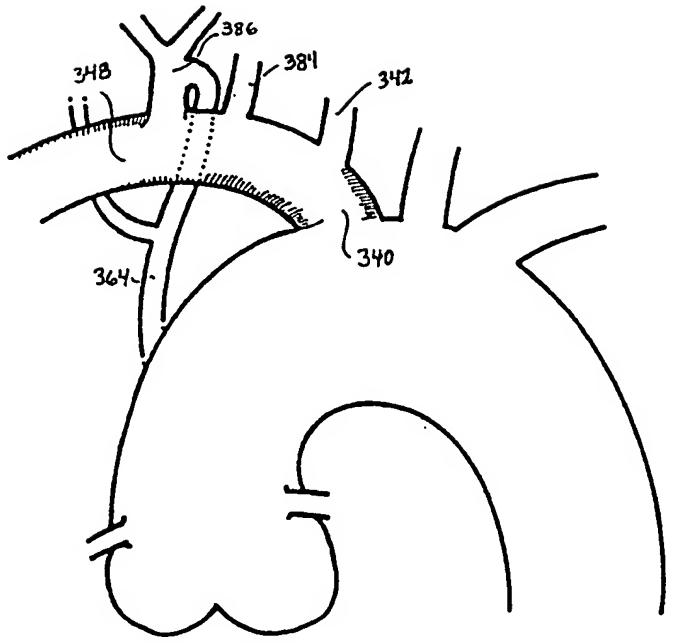


FIG. 20A

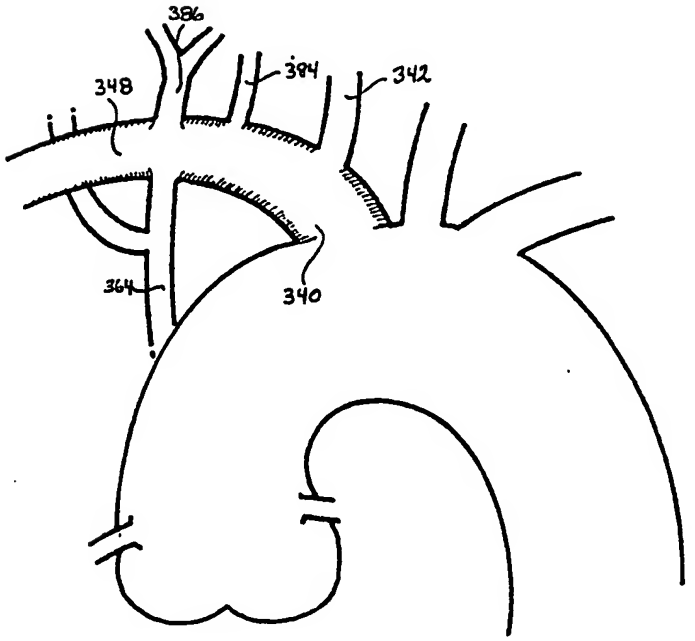
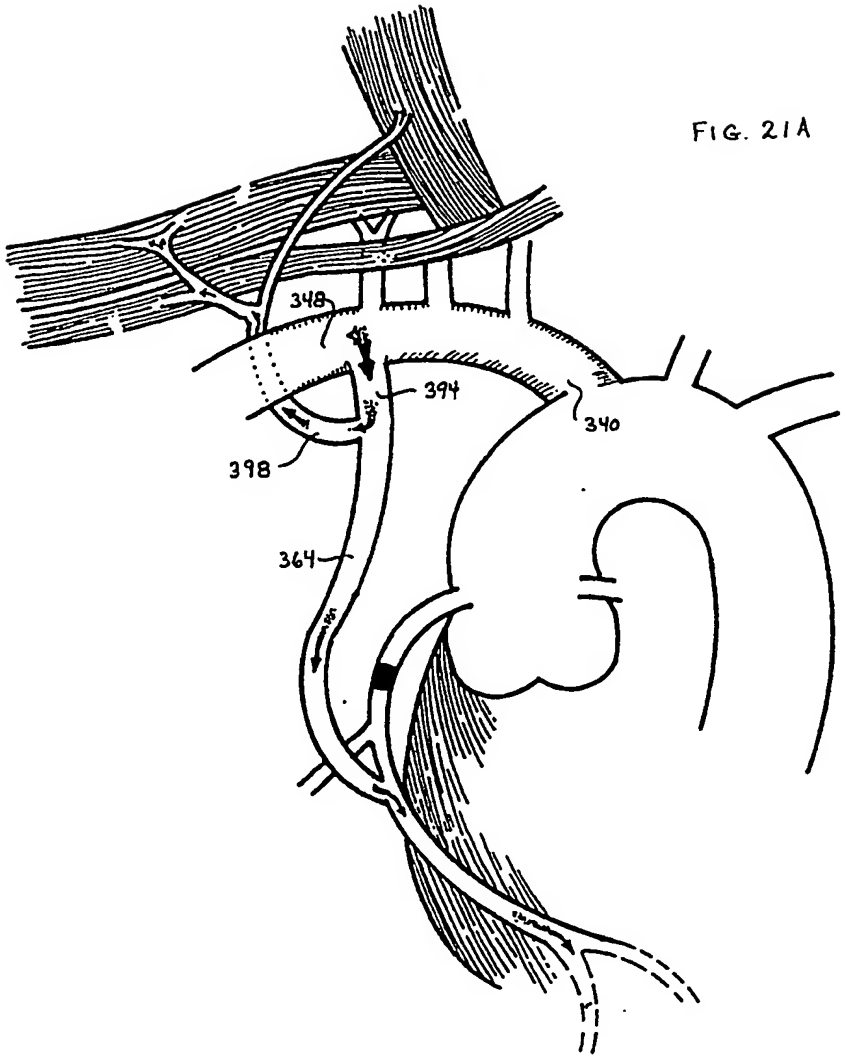


FIG. 20B

FIG. 21A



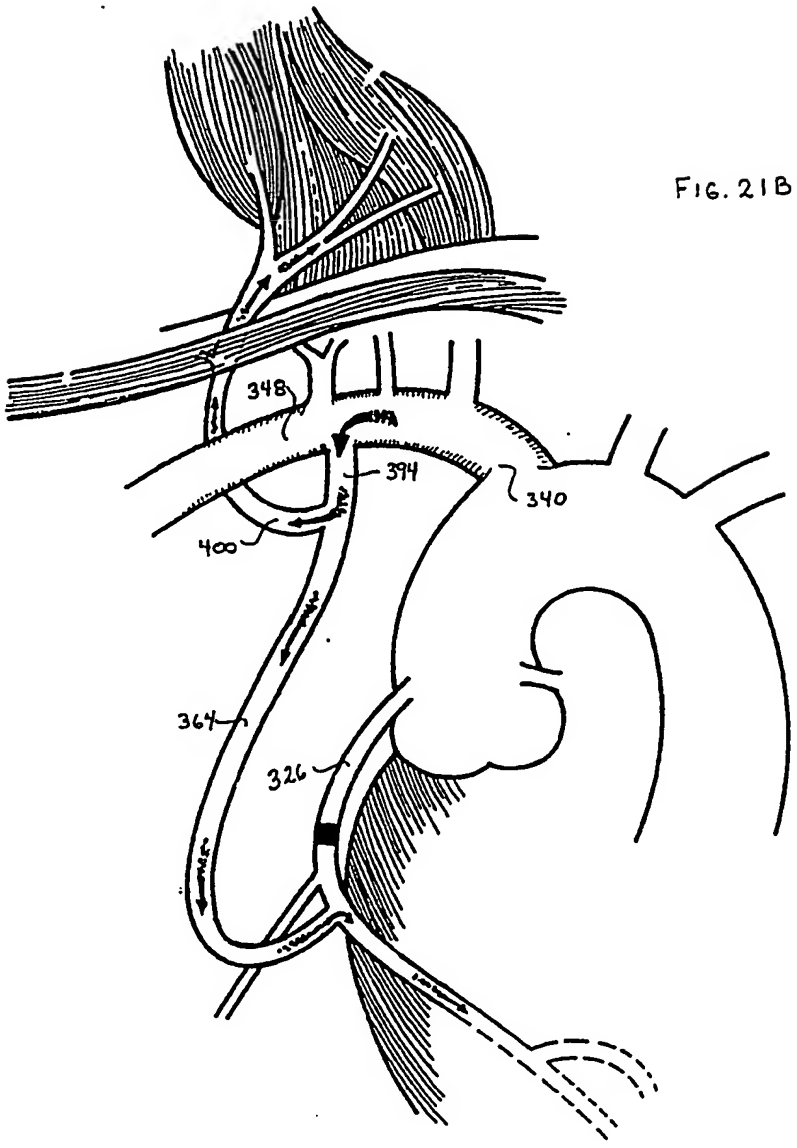
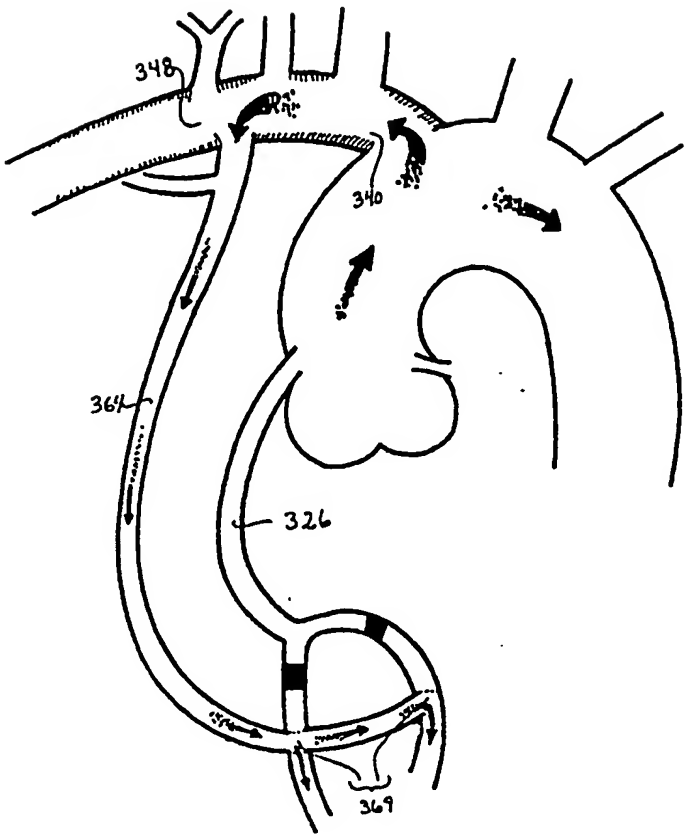


FIG. 21B

FIG. 22



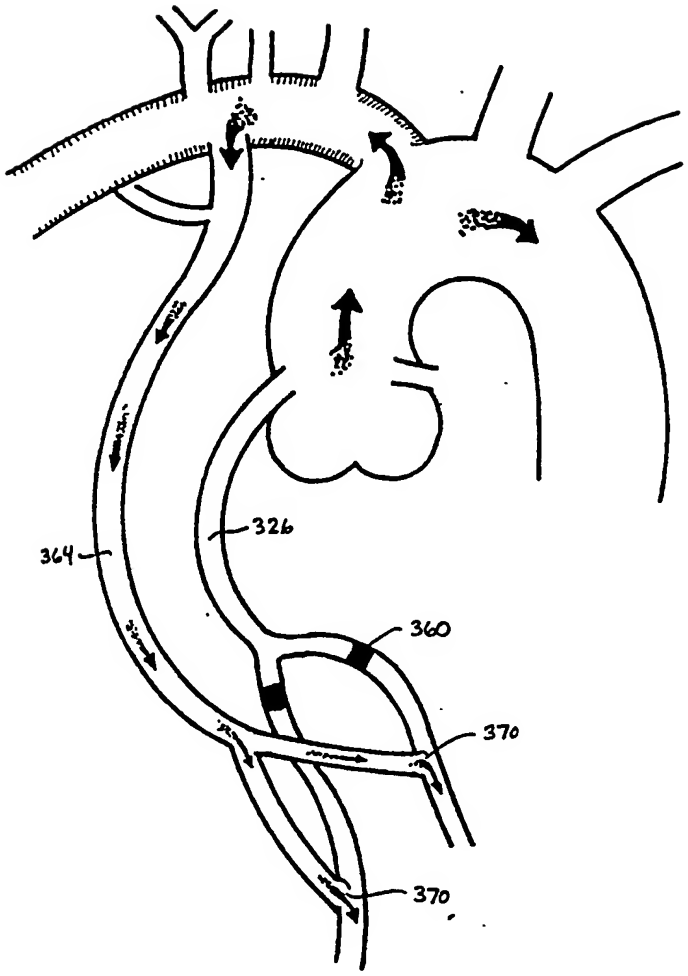


FIG. 23

FIG. 24A

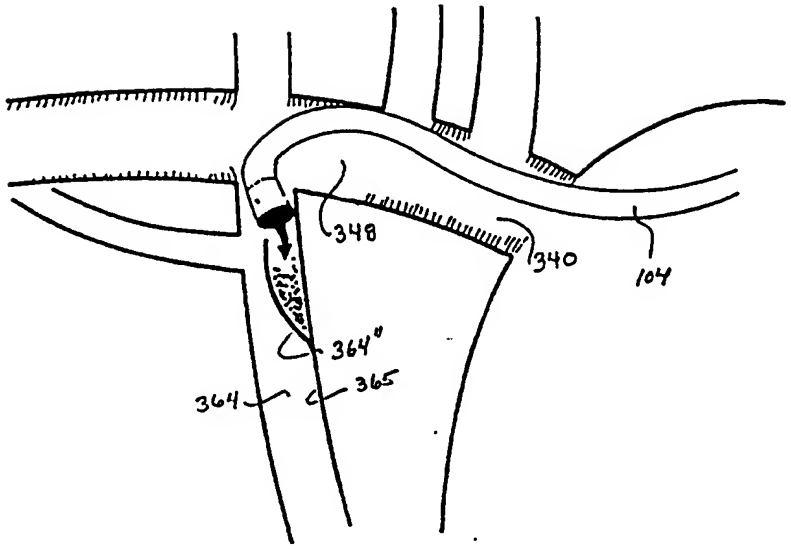


FIG. 24B

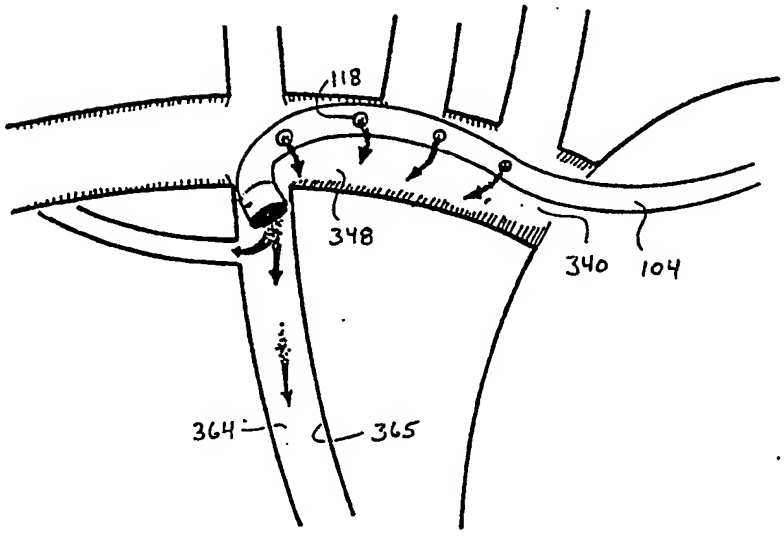
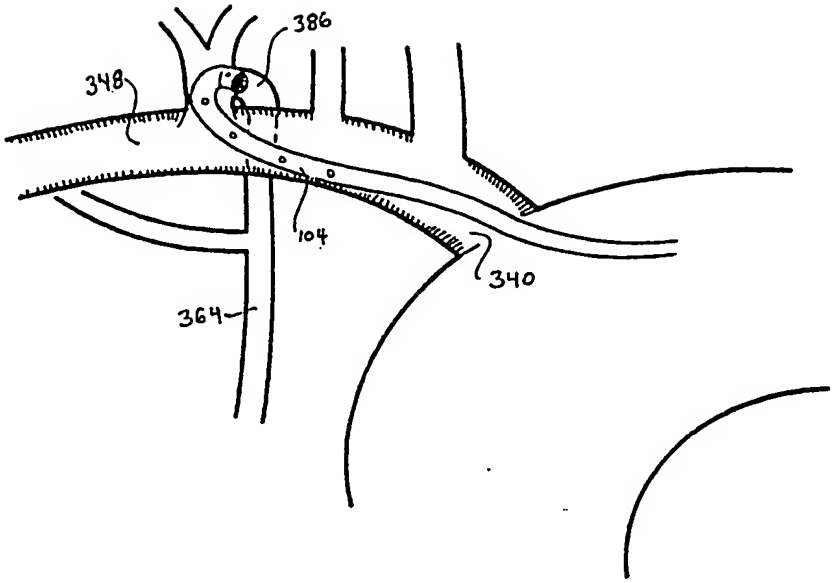


FIG. 24C



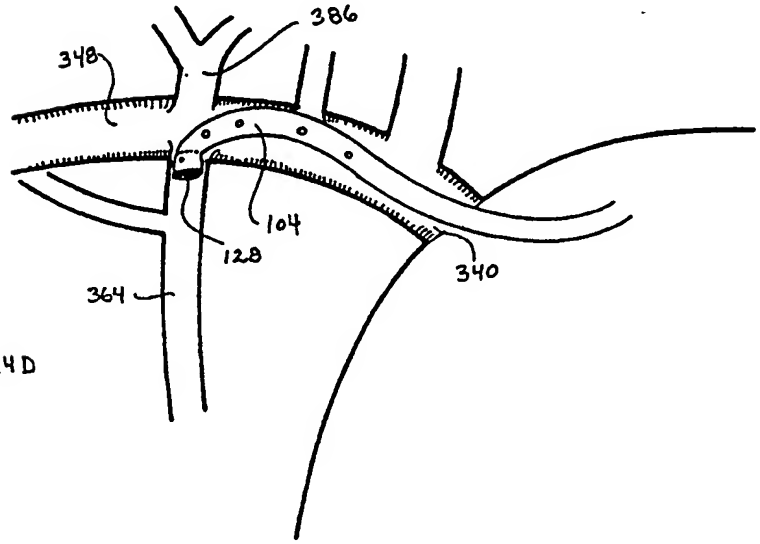


FIG 24D

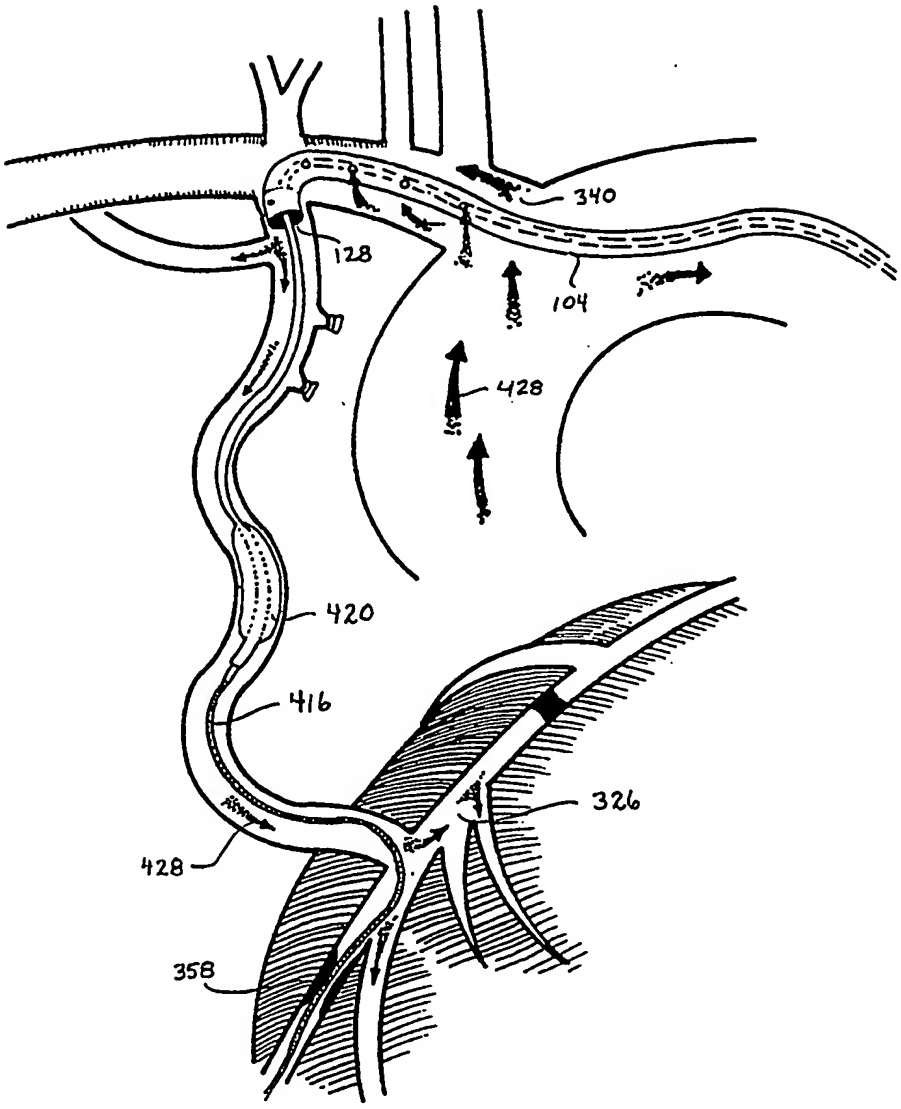


FIG. 25

FIG 26A

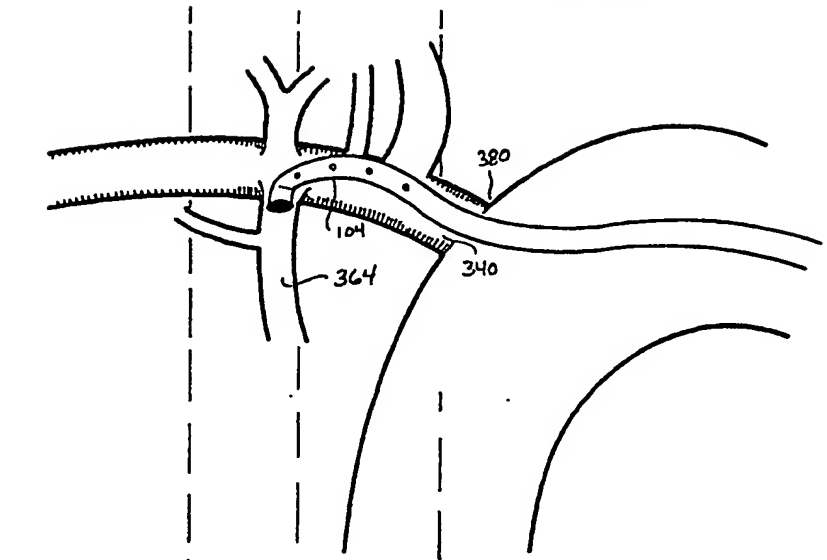


FIG. 26B

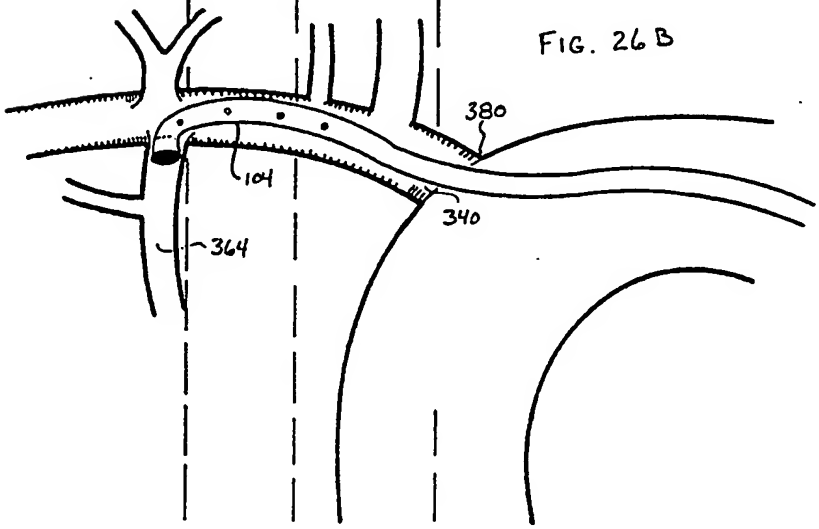


FIG. 27A

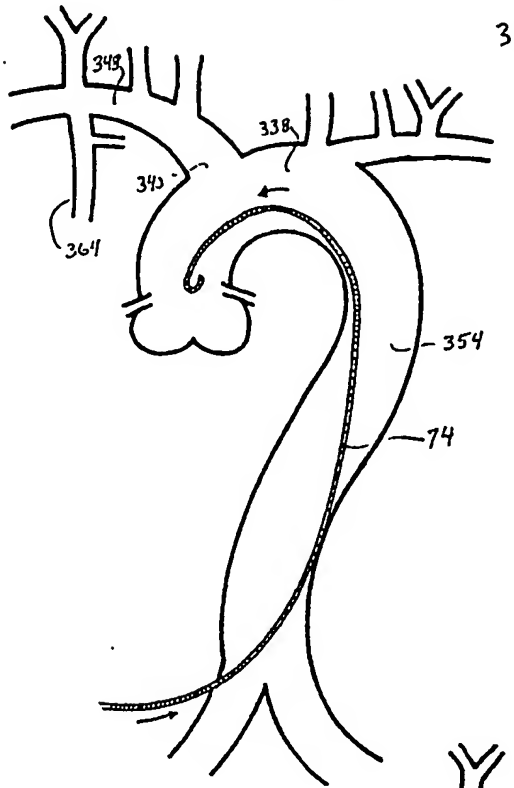
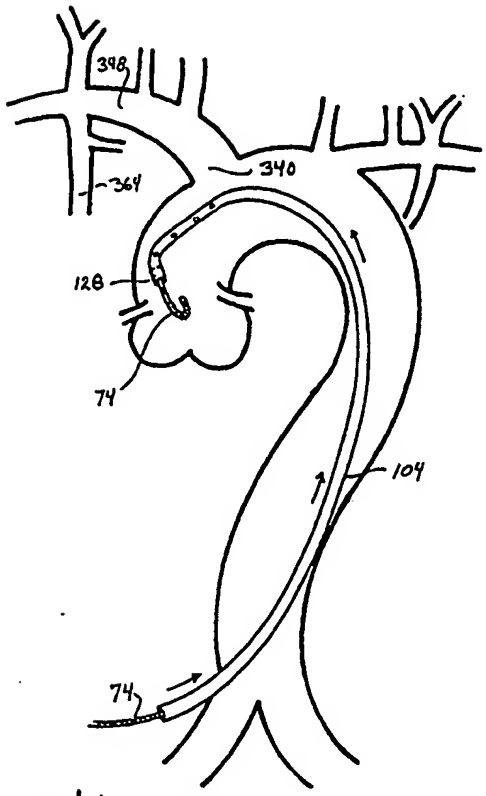


FIG. 27B



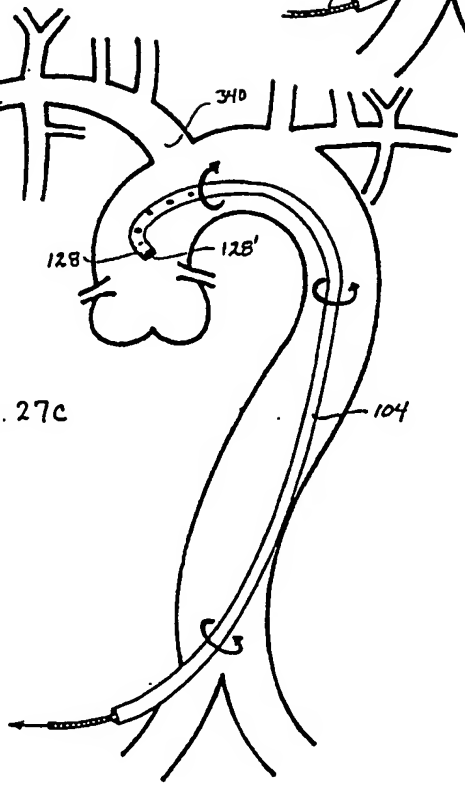


FIG. 27C

FIG 27D

FIG. 27E

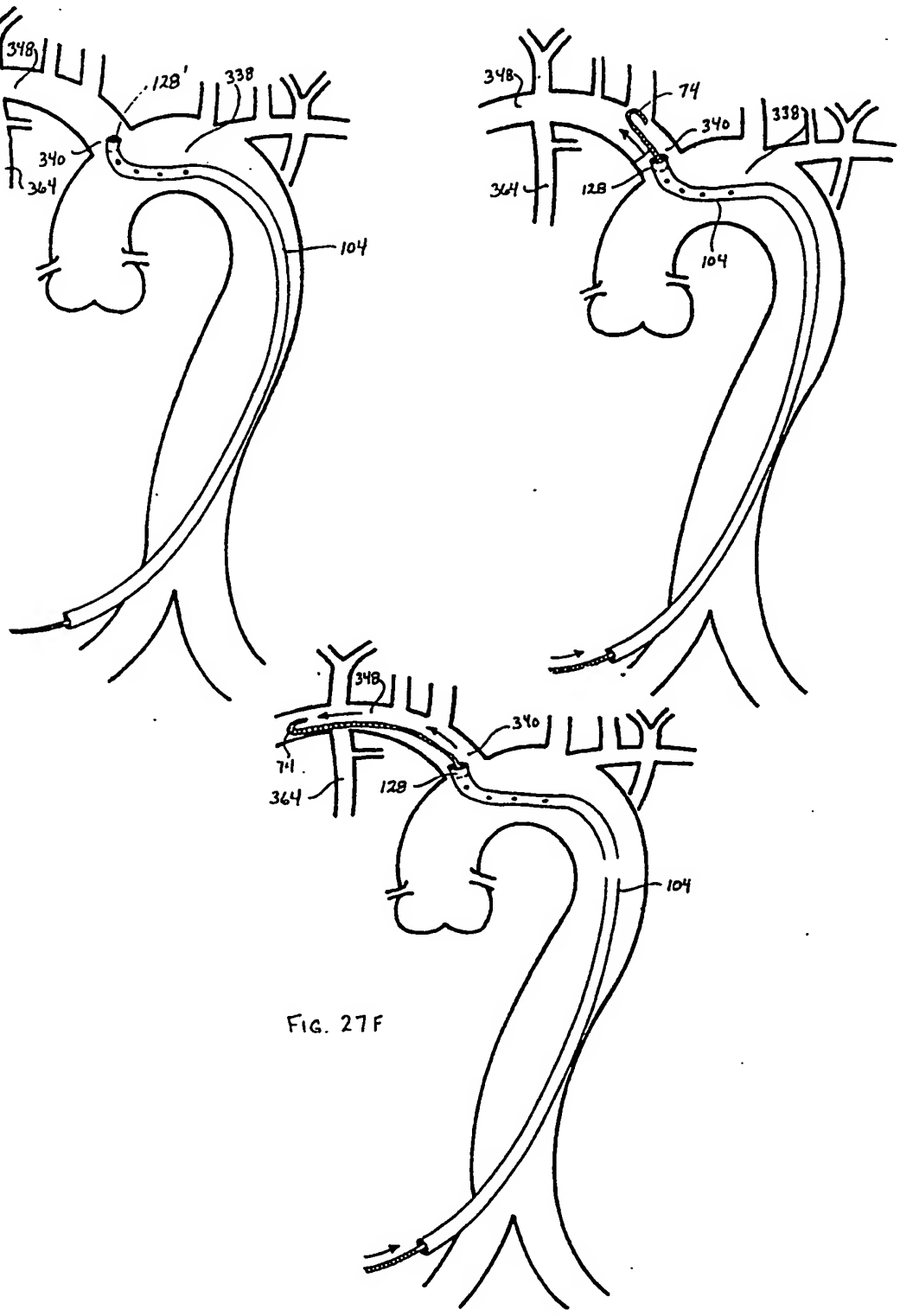
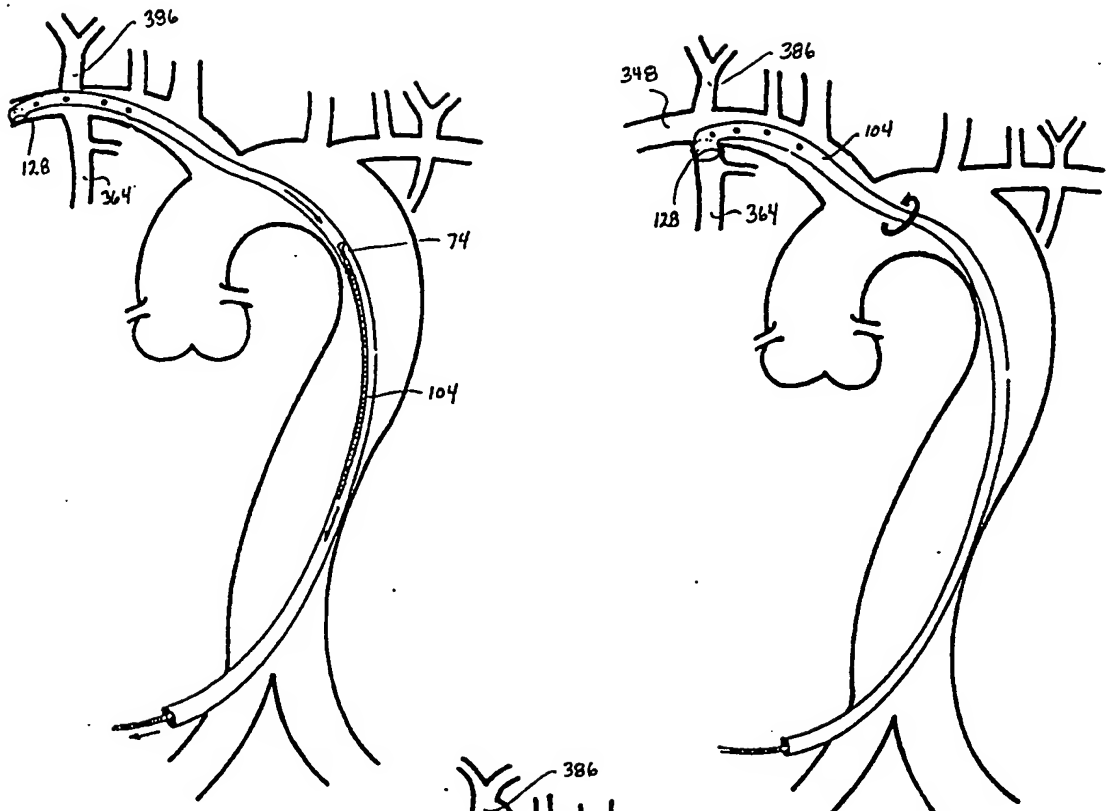


FIG. 27F

FIG 27 G

FIG. 27 H



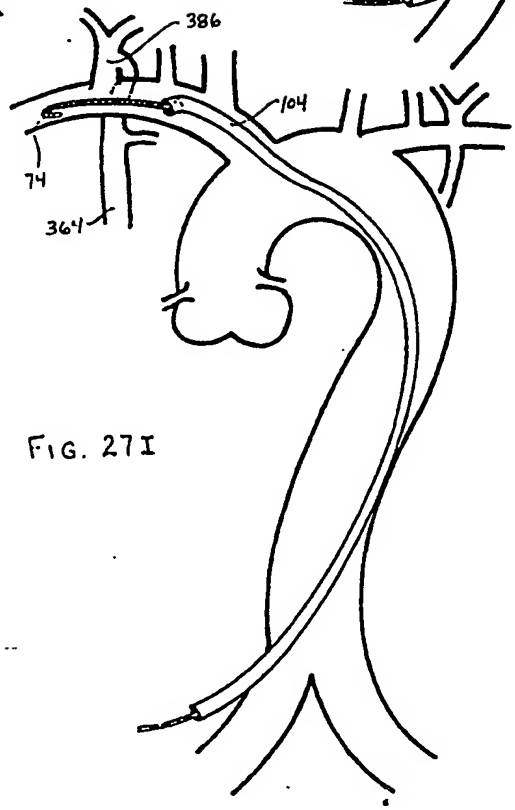


FIG. 27 I

FIG. 27J

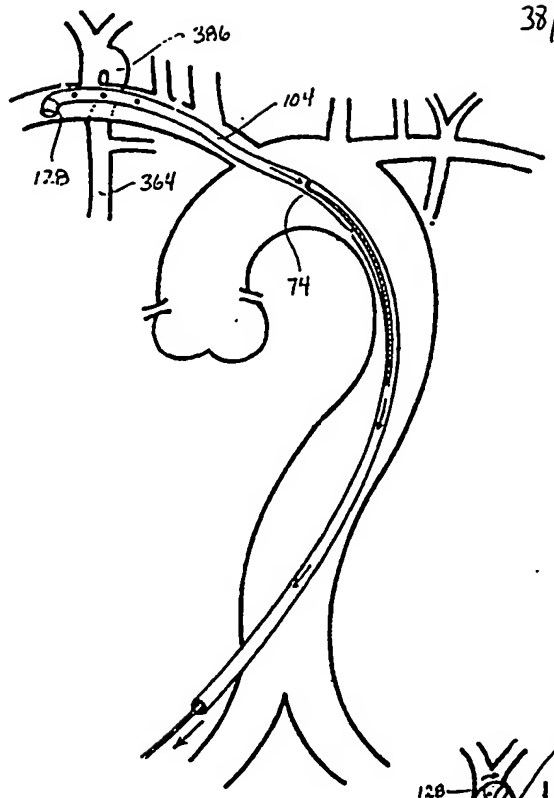
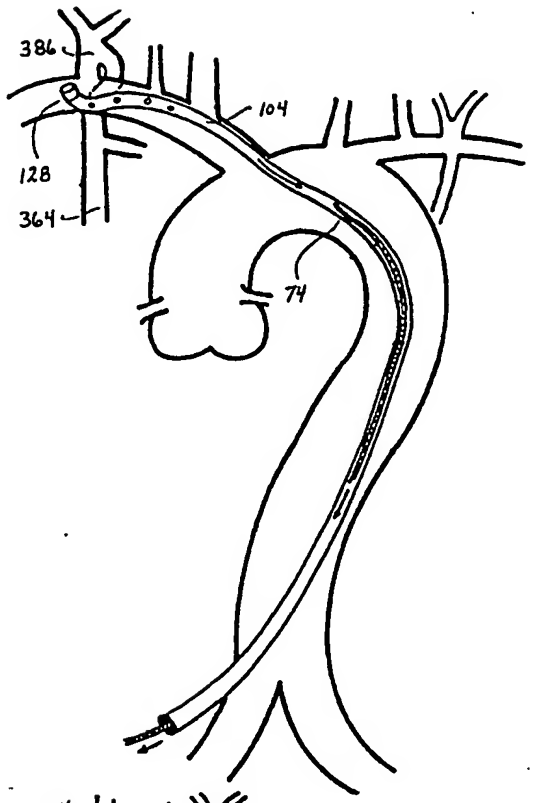


FIG. 27K



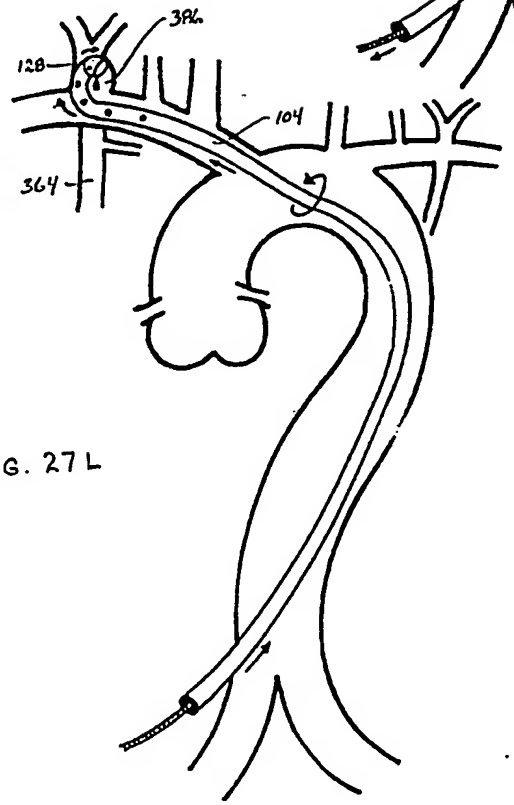


FIG. 27L

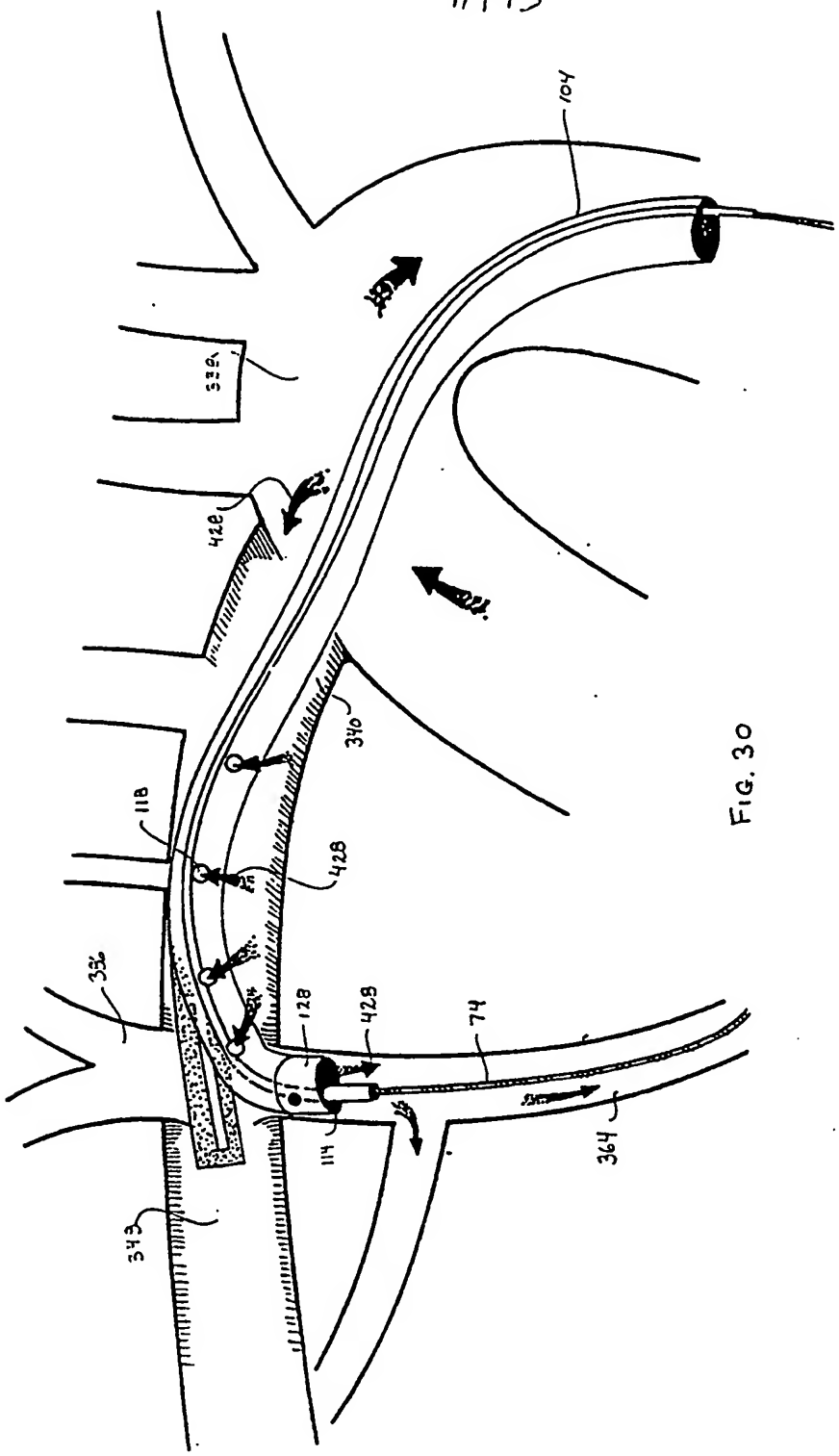


FIG. 30

FIG. 31

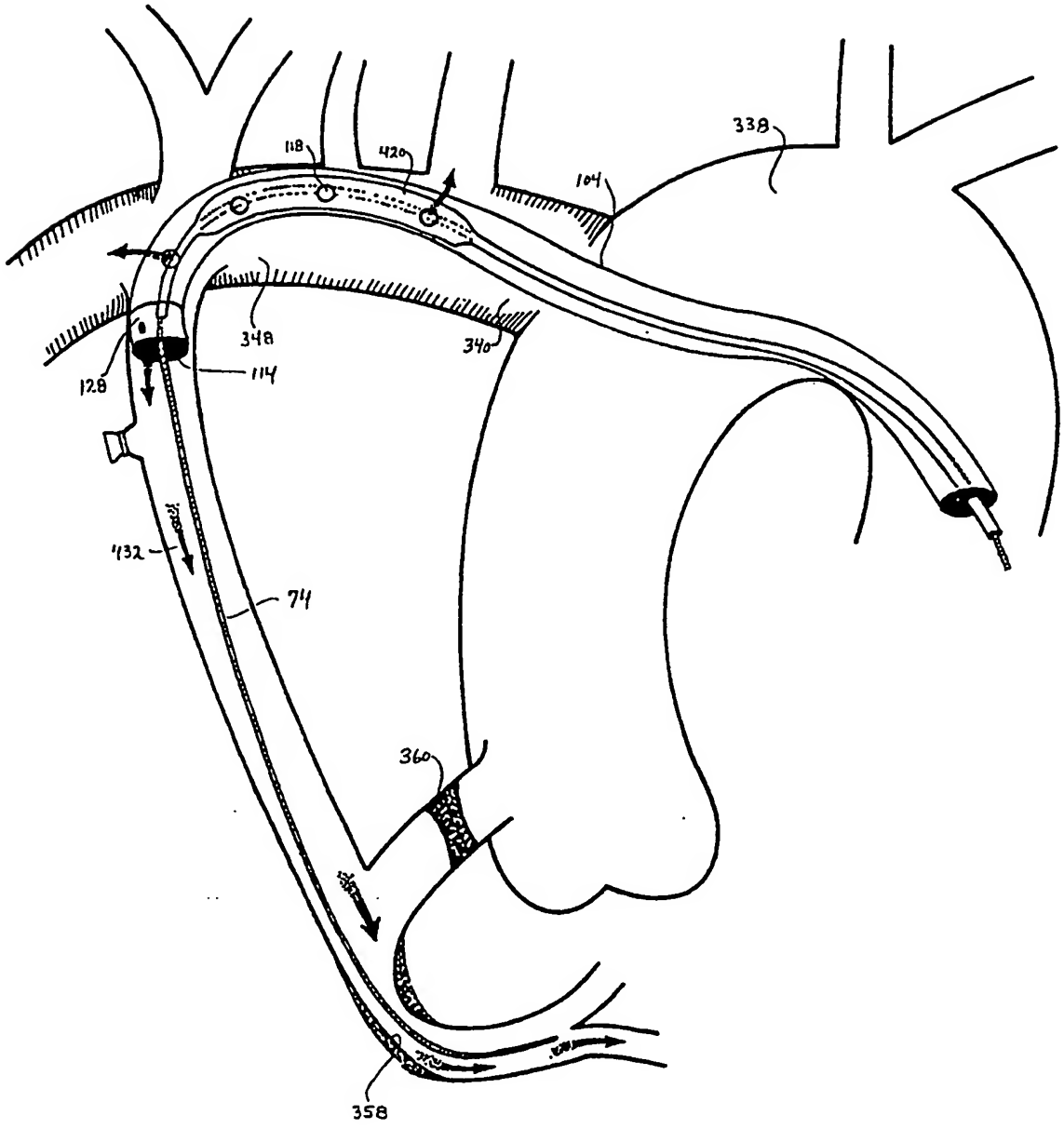
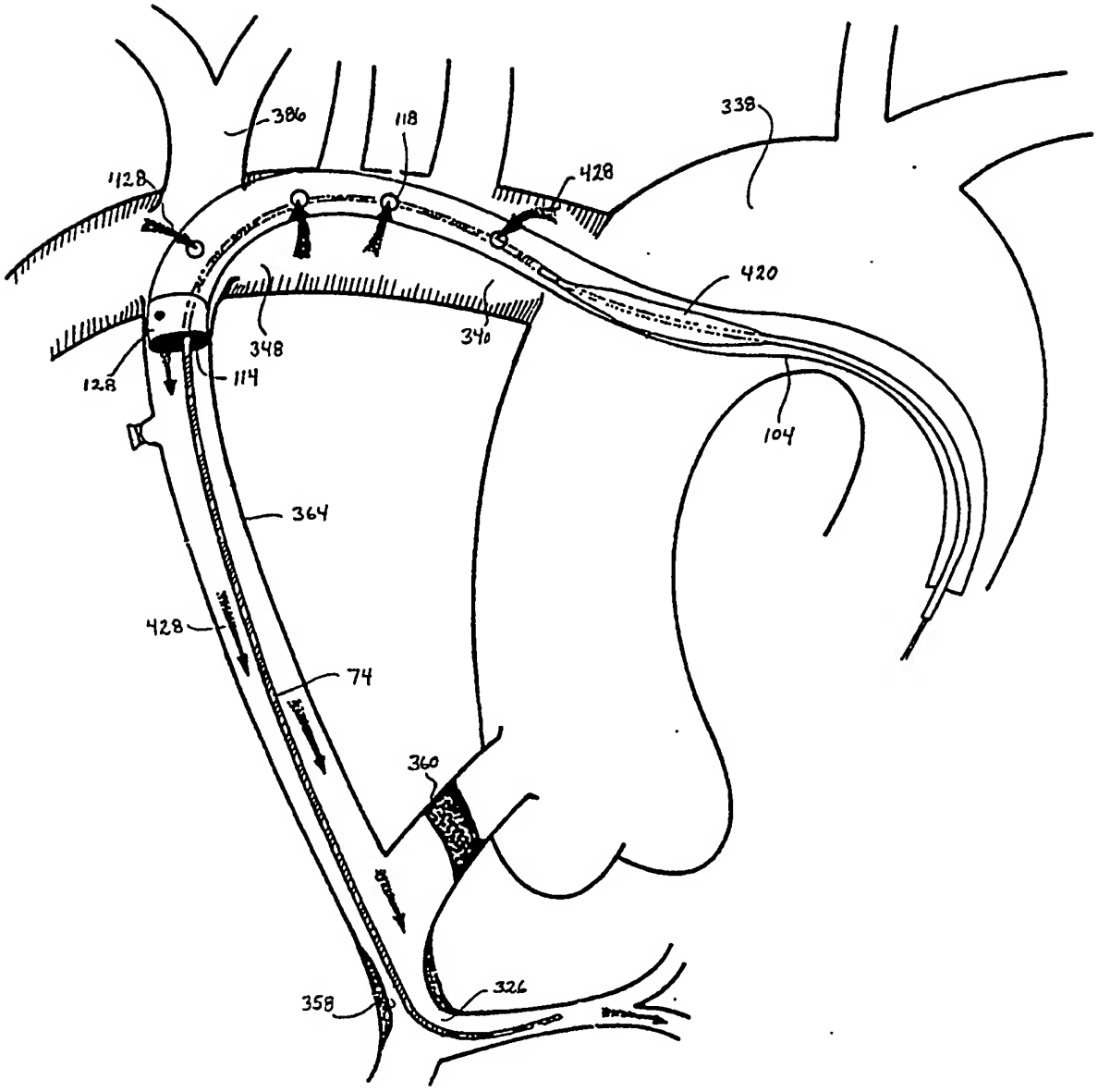


FIG. 32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INTERNATIONAL SEARCH REPORT

PCT/US 92/03430

International Application No.

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M25/00

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
X	US,A,4 882 777 (NARULA) 21 November 1989 see column 2, line 40 - line 56; claims; figures	1-14
X	US,A,4 169 464 (OBREZ) 2 October 1979 cited in the application see the whole document	1-14
A	EP,A,0 323 738 (SHERWOOD MEDICAL COMPANY) 12 July 1989 see column 6, last paragraph; claims; figures	1-14
A	EP,A,0 303 487 (C.R. BARD, INC.) 15 February 1989 see column 4, line 16 - line 20; figure 1	10

° Special categories of cited documents : [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
16 SEPTEMBER 1992	30.09.92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	MIR Y GUILLEN V.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/03430

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 15-20
because they relate to subject matter not required to be searched by this Authority, namely:

Please see PCT-Rule 39.1(iv)

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 9203430 SA 61083

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on 16/09/92
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-4882777	21-11-89	None		
US-A-4169464	02-10-79	None		
EP-A-0323738	12-07-89	US-A-	4883058	28-11-89
		JP-A-	1238872	25-09-89
		US-A-	4973306	27-11-90
		US-A-	5016640	21-05-91
EP-A-0303487	15-02-89	US-A-	4863442	05-09-89
		AU-B-	621548	19-03-92
		AU-A-	2067488	16-02-89
		JP-A-	1068276	14-03-89